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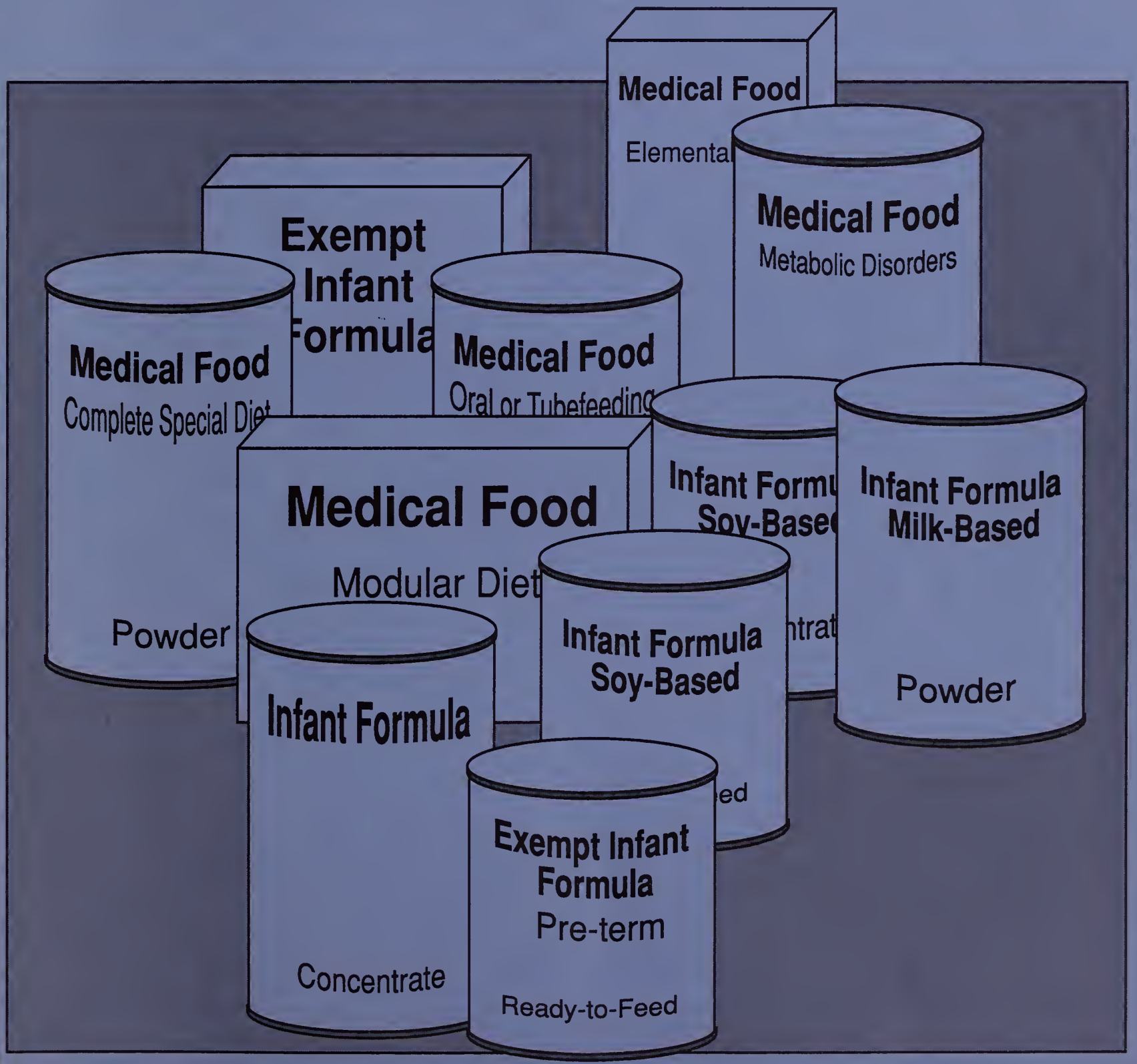


United States
Department of
Agriculture

Food and
Nutrition
Service

FNS-268

Infant Formulas, Exempt Infant Formulas, and Medical Foods Eligible for Use in WIC



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September 1990

Note to the Reader

The Food and Nutrition Service (FNS), United States Department of Agriculture, has prepared this reference to assist FNS Headquarters, and regional office personnel, and State Nutrition Coordinators for the Special Supplemental Food Program for Women, Infants, and Children (WIC) by providing information on infant formulas, exempt infant formulas, and medical foods. The reference includes information on:

- special features and composition
- purpose and function
- intended user
- general cautions to be considered in the use of products
- list of resources from each formula company

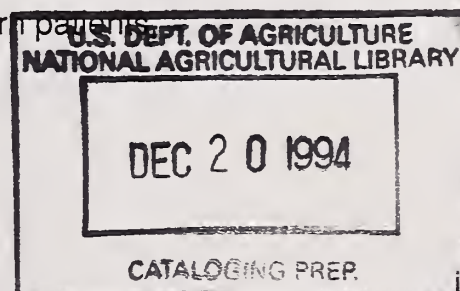
Formulas Covered in the Reference

This reference provides general information on 121 commercial formulas, exempt infant formulas, and medical foods that are available today and eligible for use in the WIC Program. All products listed in this reference are covered by trademarks to protect the proprietary interests of the companies represented.

Exclusions

For consistency with the current regulations, several types of formulas are not authorized for use in the WIC food package and therefore have been excluded from this reference, as listed below.

- products used for the sole purpose of weight management are not included in this guide since the WIC regulation does not allow WIC infants, children, and women to receive formula solely for managing their weight. The Department believes that weight should be controlled by changing dietary habits rather than by relying on formulas. However, under special documented conditions, a low-calorie product (less than 20 Cal/oz) has been allowed in the WIC Program. A high-calorie product may be appropriate for a participant who is debilitated due to extensive surgery, disease, or medical therapy. Formulas or medical foods may be used for medical conditions where maintaining body weight or achieving recommended weight gain and meeting nutrient needs may be difficult without the use of a product with a special formulation,
- oral electrolyte solutions formulated to supply water and electrolytes for maintenance or replacement of mild or moderate fluid losses are not included in this guide since they are not WIC eligible products,
- formulas that are only for hospitalized persons (except preterm formulas that may be given to the infant during the first few weeks at home),
- formulas that are only for the oncology or burn patients,
- parenteral nutritional products,



- general powder/crystallized formulas that are nutritionally incomplete unless mixed with milk, (benefits of such formulas can be supplied by formulas included in this guide), or
- supplemental puddings. However, we acknowledge that periodically such formulations may be provided to a WIC child who has impaired oral-motor skills.

Appendixes

For easy reference, the appendixes contain information on the caloric density; protein, carbohydrate, and fat source(s), in their order of predominance, and their caloric distribution; osmolality; iron content; and packaging information. The title and number for all appendixes correspond to the numbered section as outlined in the Table of Contents and in the text.

Index

The index on page 77 lists, alphabetically and primarily by feature(s), the appropriate formula(s), product company, and page in the text where the formula is discussed.

Update

Periodically, this reference will be updated. Your comments and suggestions on the usefulness, understandability, and completeness of this reference would be helpful in revising the publication. Please let us hear from you. Address all comments to the attention of: Nutrition and Technical Services Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 609, Alexandria, Virginia 22302.

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I. Introduction

The prevailing opinion of the pediatric community and manufacturers of infant formulas is that infants should be breastfed whenever possible. However, when the mother cannot or chooses not to breastfeed, commercial formulas can meet the nutrient needs of infants. When necessary, a formula may be modified and individualized to meet a specific nutritional need.

Over time, research in the areas of medicine, nutritional science, food technology, and analytical chemistry has improved the quality and acceptability of formulas and has expanded their use. Most infant formulas have been designed to meet the needs of full-term, healthy infants, while special formulas have been designed for infants, children, and adults with various inborn errors of metabolism, formula intolerance, malabsorption problems, and other nutritional or medical disorders. The Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (DHHS) makes a distinction between two types of special formulas: exempt infant formulas and medical foods.

This reference will discuss three categories of formulas: infant formulas (generally recognized as standard infant formulas), exempt infant formulas, and medical foods. Infant formulas include milk-based and soy-based formulas designed for full-term, healthy infants. A combination milk- and soy-based formula is included for older infants. Exempt infant formulas include formulas for infants with an inborn error of metabolism, low birthweight, or an unusual medical or dietary problem. Exempt infant formulas are primarily formulated for infants less than 1 year old. Medical foods include diets for metabolic disorders, complete special diets, complete elemental diets, and incomplete modular diets. Medical foods are intended for children 1 year old and older, and for adults. The distinguishing features of the three categories of formulas are identified below.

"Infant formula" means a "food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk" (P.L. 96-359, the Infant Formula Act of 1980, enacted September 26, 1980, as amended by the Drug Enforcement, Education, and Control Act of 1986). The law specified the nutrient requirements for infant formulas. Effective January 14, 1986, the nutrient requirements for infant formulas were modified to reflect the latest recommendations from the Committee on Nutrition/ American Academy of Pediatrics (CON/AAP) for meeting the total nutritional needs of the normal infant (50 FR 45106, October 30, 1985). Also, these laws provided the FDA the authority to promulgate specific quality assurance testing and procedures, labeling requirements, and the terms and conditions that manufacturers must meet to continue exemptions.

The Infant Formula Act of 1980 and the 1986 amendments exempted some infant formulas from meeting the nutrient requirements, recognizing that standard infant formula nutrient profiles would be inappropriate and medically contraindicated for some infants.

"Exempt infant formula" means an "infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have inborn errors of metabolism or low birthweight, or who otherwise have unusual medical or dietary problems" (50 FR, 48183, November 22, 1985).

"Medical food" means a "food which is formulated to be consumed or administered enterally under supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation" (P.L. 100-290, The Orphan Drug Amendments of 1988, April 18, 1988).

Infant formulas, exempt infant formulas and, with some exceptions, medical foods, are made available through the WIC Program, which serves as an adjunct to other maternal and child health programs. The WIC regulations define formulas authorized for use in the WIC food packages according to the participant's medical conditions rather than formula composition.

Exempt infant formulas and medical foods are covered under the term "special formulas" in the WIC regulations. Special formulas are authorized when a physician determines and documents that the participant has a medical condition that restricts the use of conventional formulas or foods and necessitates the prescription of a special formula. The physician's documentation must be included in the participant's certification file. Special formulas included in this update are designed to be used for oral feeding only or for either oral or tube feeding. **They are only intended for enteral digestion and should not be used for parenteral nutrition.**

For the purpose of this reference, products that can support the growth of an individual are designated as nutritionally complete. Products that consist of a single or mixed nutrient source that cannot support the growth of an individual are designated as nutritionally incomplete.

II. Infant Formulas, Exempt Infant Formulas, and Medical Foods by Category

For the purposes of this reference the three categories of formulas are further subdivided into a total of 10 classes of formulas:

- Infant Formulas for Full-Term Infants
 - Milk-Based
 - Soy-Based
 - Combination Milk- and Soy-Based
- Exempt Infant Formulas
 - Preterm and Low-Birthweight Infants
 - Metabolic Disorders
 - Other Unusual Medical or Dietary Problems
- Medical Foods
 - Diets for Metabolic Disorders
 - Complete Special Diets
 - Complete Elemental Diets
 - Incomplete Modular Diets

A general discussion is included for each class. At the end of each discussion, formulas that fit into the specific class are described in detail. Where appropriate, a caution statement is also provided. This statement contains information provided by the company literature. In the appendixes, tables representing each of the 10 classes show all formulas that are generally placed in each class. Each table shows the following information taken from company literature, if available:

- the manufacturer
- the caloric density
- protein, carbohydrate, and fat sources
- osmolality and iron content
- caloric distribution
- packaging information including forms and powder yield, if appropriate

Osmolality information has been included because it is an important determinant of formula tolerance. Osmolality refers to the actual osmotic tension in the formula and is expressed as the mOsm/kg of water; it is directly related to the concentration of molecular or ionic particles in solution, and inversely to the concentration of water (Tomarelli, R.M., 1976). If the osmolality of the formula is too high, "it may draw water from the intestinal wall, interfere with nutrient and water absorption, and/or cause diarrhea" (Hansen, et al, 1988).

Iron content is listed in the text as milligrams per 100 Calories and in the appendixes as milligrams per quart. Formulas containing at least 9.5 milligrams of iron per quart meet the WIC requirement of 10 milligrams of iron per liter of formula at standard dilution. For healthy infants, only iron-fortified formulas are authorized for use in the WIC Program.

A. Infant Formulas for Full-Term Infants

A-1. Infant Formulas: Milk-Based

The composition of cow's-milk-based formulas is designed to simulate human milk in caloric distribution and digestibility. This is accomplished by (a) diluting the protein in cow's milk, (b) replacing the poorly absorbed butterfat with oils that are more easily absorbed, and (c) adding carbohydrate (Sarett, 1981).

Infant formulas generally contain 20 Calories per fluid ounce (68 Kcal/dl) of metabolizable energy. However, under a physician's care, the dilution may be altered to increase or decrease a caloric density so that it is appropriate for the infant's medical needs.

Unlike human milk, cow's milk is a poor source of taurine, an amino acid which may be involved in the function of several organ systems, including the brain, the retina, the heart, and the liver (Rassin, Sturman, and Gaull, 1978). Several companies now add taurine to many of their infant formulas (including exempt formulas) in amounts similar to the level found in human milk.

Infant formulas manufactured and distributed in the United States must contain added vitamins and minerals in accordance with the Infant Formula Act of 1980 and the Revision and Codification of Nutrient Requirements (21 CFR Part 107.100 Subpart D). Most infant formulas are iron fortified. Some companies also provide low-iron formula. Use of low-iron formulas is not allowed in the WIC Program without medical documentation of need.

Below is a detailed description for each of the milk-based infant formulas, by company. The formulas are nutritionally complete and are intended to meet the needs of the full-term, healthy infant who is not breastfed or is partially breastfed. Some formulas may be needed by children and adults as well as infants in the WIC Program. Also listed is a cow's-milk-starter formula containing partially hydrolyzed whey protein.

These products should not be used for parenteral nutrition. Appendix A-1 provides a quick reference for additional information on these formulas.

Carnation Company

Carnation Good Start with Iron: A nutritionally complete, partially hydrolyzed cow's milk whey-protein-formula with added taurine and L-carnitine. Contains lactose. For nonbreastfed infants or as a supplement for breastfed infants. May be used for infants who have not shown any symptoms of milk allergy and are fed Good Start from birth. The cow's milk-whey-protein source is specially processed to make the formula less allergenic than intact cow's milk formula when fed from birth. Contains 1.5 milligrams of iron per 100 Calories.

Caution: THIS FORMULA SHOULD NOT BE USED IN THE MANAGEMENT OF INFANTS WHO HAVE ALREADY DEVELOPED ALLERGIES OR SENSITIVITIES TO COW'S MILK PROTEIN. For children with suspected cow's milk allergy, product should be used only under a physician's supervision.

Carnation Follow-up Formula with Iron: A nutritionally complete, milk-based followup formula. Specifically designed to complement the diet of infants age 6 months or older who are routinely eating solid foods. Provides protein, iron, and added calcium essential for normal growth and development of the older infant. Contains 1.9 milligrams of iron per 100 Calories.

Caution: This formula is not intended to be used for infants who have trouble tolerating standard milk-based formulas.

Gerber Products Company

Gerber Baby Formula with Iron, Gerber Baby Formula: Nutritionally complete formulas with added taurine. Gerber Baby Formula with Iron contains 1.8 milligrams of iron per 100 Calories. Gerber Baby Formula contains 0.16 milligram of iron per 100 Calories; additional iron may be required.

Mead Johnson Nutritionals

Enfamil with Iron, Enfamil: Nutritionally complete formulas with added taurine. Enfamil with Iron contains 1.88 milligrams of iron per 100 Calories. Enfamil contains 0.16 milligram of iron per 100 Calories; additional iron may be required.

Ross Laboratories

Similac with Iron, Similac: Nutritionally complete formulas with added taurine. Similac with Iron contains 1.8 milligrams of iron per 100 Calories. Similac contains 0.22 milligram of iron per 100 Calories; additional iron may be required.

Wyeth-Ayerst Laboratories

SMA, SMA lo-iron: Nutritionally complete formulas with added taurine. SMA contains nucleotides in amounts similar to those found in human milk and contains 1.8 milligrams of iron per 100 Calories. SMA lo-iron contains 0.2 milligram of iron per 100 Calories; additional iron may be required.

A-2. Infant formulas: Soy-Based

Soy-based, milk-free formulas have been developed for infants who cannot tolerate the protein or lactose in milk-based formulas. These formulas are generally similar in their overall nutrient composition and caloric density to the milk-based formulas, but have a different source of protein. They are lactose-free and the carbohydrate source is generally sucrose, corn syrup, or glucose polymers (corn syrup solids) or a combination of these sources. The amino acid methionine is added to upgrade the quality of the protein to equal that of casein in cow's milk. In addition, carnitine is now being added to many formulas. This dietary factor has been shown to have a role in the oxidation of long-chain fatty acids (Fritz, 1963). Similar to milk-based formulas, the amino acid taurine (see page 5) is also added to soy-based formulas.

Soy-based formulas may be used as an alternative to milk-based formulas when a milk-free diet is indicated. Clinical data show that 10 to 20 percent of the infants who exhibit clinical symptoms of cow's milk intolerance also develop soy-based intolerance. For some infants, the benefit of using soy-based formulas may be due to the replacement of lactose by sucrose and/or corn syrup and not due to the protein (Committee on Nutrition, 1985). Lactose-free, soy-based formulas are sometimes used to avoid lactose-associated diarrhea or as a post-diarrhea formula.

Results from studies using soy-based formulas have shown that full-term infants progress very well. However, the welfare of preterm infants fed soy-based formulas is not clear. Data on growth (length and weight) and serum albumin levels have shown that preterm infants fed soy-based formulas (methionine supplemented) and preterm infants fed cow's milk-based formulas do not always do equally as well (Committee on Nutrition, 1983). There are also reports that very low-birthweight infants fed soy-based formulas for several months developed osteoporosis and rickets. However, this is also true with milk-based formulas and human milk feedings (Committee on Nutrition, 1985).

The Committee on Nutrition/American Academy of Pediatrics (CON/AAP) recommends the use of soy-based formulas under the following conditions:

- vegetarian families where animal protein formulas are not desirable;
- the management of galactosemia, primary lactase deficiency, and during recovery of secondary lactose intolerance; and
- potentially allergic infants (with a family history of atopy) who have shown clinical manifestations of allergy.

However, the CON/AAP recommends that these infants be monitored closely for allergy to soy protein (Committee on Nutrition, 1983).

The CON/AAP further recommends that soy-based formula should not be used under the following conditions:

- for the routine feeding of premature and low-birthweight infants (If it must be used, use should be for a limited period.);

- in the dietary management of documented clinical allergic reactions to cow's milk protein and/or soy-based formula; and
- in the routine management of colic.

Protein hydrolysate-based formulas are used sometimes for infants sensitive to intact proteins of milk and other foods. These formulas contain enzymatically hydrolyzed or partially hydrolyzed casein. The nitrogen sources in these formulas are essentially free amino acids and simple polypeptides.

Soy-based formulas manufactured and distributed in the United States must contain added vitamins and minerals in accordance with the Infant Formula Act of 1980 and the Revisions and Codification of Nutrient Requirements (21 CFR Part 107.100, Subpart D).

Below is a detailed description of the soy-based formulas, by company. The formulas are nutritionally complete and are intended to meet the needs of the full-term, healthy infant who may be allergic to milk protein or lactose intolerant. All soy-based infant formulas are fortified with iron. Some soy-based infant formulas are needed by children and adults as well as infants.

These products should not be used for parenteral nutrition. Appendix A-2 provides a quick reference for additional information on these formulas.

Loma Linda Foods

Soyalac: A nutritionally complete milk-free formula with added L-methionine, taurine, and L-carnitine. Based on an extract of the whole soybean. For infants, children, and adults with an intolerance to cow's milk or lactose or who have galactosemia. Also useful with common feeding problems associated with vegetarianism. Contains 1.9 milligrams of iron per 100 Calories.

I-Soyalac: A nutritionally complete, milk-free, corn-free, soy isolate formula with added L-methionine, taurine, and L-carnitine. Contains no animal products. For infants, children, and adults with an intolerance to cow's milk, lactose, or corn derivatives or who have galactosemia. Also useful with common feeding problems associated with vegetarianism. Contains 1.9 milligrams of iron per 100 Calories.

Mead Johnson Nutritionals

ProSobee: A nutritionally complete, milk-free, lactose-free, sucrose-free formula with added selenium, L-methionine, taurine, and L-carnitine. For infants who are intolerant to milk or are lactose or sucrose intolerant, or have galactosemia. Also appropriate for children and adults. May be used as a milk substitute for persons with a poor tolerance of milk. ProSobee powder contains coconut and corn oils; Prosobee liquid concentrate contains coconut and soy oils. Contains 1.88 milligrams of iron per 100 Calories.

Ross Laboratories

Isomil: A nutritionally complete, milk-free, lactose-free formula with added L-methionine, taurine, and L-carnitine. For infants intolerant to cow's milk. May be used with lactase deficiency, lactose intolerance, and galactosemia. Also appropriate for children and adults. Contains 1.8 milligrams of iron per 100 Calories.

Isomil SF: A nutritionally complete, milk-free, lactose-free, sucrose-free formula with added L-methionine, taurine, and L-carnitine. For infants intolerant to cow's milk or intolerant to sucrose or lactose. Use with disorders where lactose and sucrose should be avoided. Also appropriate for children and adults. Contains 1.8 milligrams of iron per 100 Calories.

Wyeth Laboratories

Nursoy: A nutritionally complete, milk-free, lactose-free formula with added L-methionine, taurine, and L-carnitine. For infants who, for medical reasons, cannot receive cow's milk and/or who have lactase deficiency, lactose intolerance, or galactosemia. Also appropriate for children and adults. Nursoy powder contains corn syrup solids; Nursoy ready-to-feed and liquid concentrate contain sucrose and can be used for infants, children, and adults who cannot receive corn derivatives. Contains 1.7 milligrams of iron per 100 Calories.

A-3. Combination Milk- and Soy-Based

A combination milk- and soy-based formula has been designed for older infants and toddlers. The product is fortified with recommended levels of vitamins and other minerals to complement the solid food diet of older infants. Below is a detailed description for this milk/soy-based infant formula. **This product should not be used for parenteral nutrition. Appendix A-3** provides a quick reference for additional information on this formula.

Ross Laboratories

Advance: A nutritionally complete, milk/soy-based formula with added taurine. For older infants and toddlers. Fortified with recommended levels of vitamins and other minerals to complement the solid food diet of older infants. The combination of soy and cow's milk proteins helps reduce the risk of cow's milk-induced enteric blood loss. Contains 1.8 milligrams of iron per 100 Calories. (Caloric density is 16 Calories per fluid ounce.)

B. Exempt Infant Formulas

The Infant Formula Act of 1980 and the 1986 amendments exempt from some of its requirements specialty infant formulas that are intended for use by infants with special medical or dietary needs, including but not limited to low-birthweight infants and infants with inborn errors of metabolism. Two broad categories of exempt infant formulas exist: (1) those formulas that are generally available at the retail level, and (2) those formulas that are not generally available at the retail level. Exempt infant formulas may deviate from the nutrient and labeling requirements that apply to regular formulas, when the manufacturer has submitted to the Food and Drug Administration sufficient medical, nutritional, scientific, or technological rationale to support the deviations. In addition, for exempt infant formulas that are not generally available in the retail market, manufacturers must justify any deviations from the quality control requirements that apply to infant formulas. However, all other aspects of the Infant Formula Act must be met.

B-1. Exempt Infant Formulas: For Preterm and Low-Birthweight Infants

In 1961, the World Health Organization redefined prematurity to include gestational age as well as birthweight. In 1967, newborns were classified by weight (small, appropriate, and large) and gestational age. These definitions made it easier to identify infants with special problems and encouraged specialized care for premature infants. Today, preterm and low-birthweight infant feeding practices vary widely but are based primarily on the birthweight of the infant (Schanler, 1985).

Certain exempt infant formulas meet the needs of the premature and/or low-birthweight infant and differ from infant formulas (as discussed on pages 5-9). Preterm formulas have significantly greater levels of protein, vitamins A, C, D, and K, folate, calcium, phosphorus, magnesium, and zinc than infant formulas; several are available at 20 and 24 Calories per fluid ounce. Some preterm formulas must be supplemented with vitamin D, iron, and fluoride (Birkbeck, 1984), while others contain adequate levels of vitamin D and iron. Company instructions should be followed carefully.

Nutritionally complete exempt infant formulas designed for preterm infants and low-birthweight infants generally contain whey-predominant proteins, and a mixture of lactose and glucose polymers. They also contain a fat mixture of Medium-Chain Triglycerides (MCT) and relatively unsaturated long-chain triglycerides. MCT contain fatty acids of shorter chain length than those found in conventional formulas. MCT do not require emulsification for absorption and are more readily absorbed than longer chained fats. Medium-chain fatty acids are directly absorbed into the portal system.

Preterm formulas reflect the estimated nutrient requirement of the low-birthweight infant and take into consideration the immature infant's limited ability to digest, absorb, and metabolize the formula. Formula companies recommend the use of preterm formulas in the very-low-birthweight infant when enteral feedings are tolerated.

Breast milk may also be used for the preterm infant. A common practice is to supplement breast milk with energy (glucose polymers or MCT), lactose, vitamins, and

minerals (Bhatia and Rassin, 1988). Milk fortifiers have been specially developed to supplement breast milk. All of these products are meant to be added to breast milk; some may be alternated with the breast milk. Some milk fortifiers may also be added to formulas.

Below is a detailed description of the exempt infant formulas for the preterm infant, by company. Where applicable, the caution statement is based on information taken from company literature. **Appendix B-1** provides a quick reference for additional information on these formulas.

Mead Johnson Nutritionals

Enfamil Premature Formula with Iron, Enfamil Premature Formula (20/24 Cal): Nutritionally complete, whey-protein-based formulas with added taurine. For the rapidly growing, low-birthweight infant. Available in 20 and 24 Calories per fluid ounce. Enfamil Premature Formula with Iron contains 1.88 milligrams of iron per 100 Calories. Enfamil Premature Formula contains 0.25 milligram of iron per 100 Calories.

Caution: Initial feedings should be diluted and progressively increased to full strength over several days. Supplemental vitamin E should also be considered for the premature infant.

Enfamil Human Milk Fortifier: Nutritional supplement to be added to mother's milk for premature infants. Contains no iron. Add to mother's milk beginning at 2-4 weeks old, when the premature infant is rapidly growing. When mixed with human milk, it increases the levels of protein, energy, calcium, phosphorus, other minerals, and selected vitamins to levels nutritionally balanced to meet the needs of the rapidly growing low-birthweight infant.

Ross Laboratories

Similac Special Care with Iron (24 Cal), Similac Special Care (20/24 Cal): Nutritionally complete formulas with added taurine and L-carnitine. For the clinically stable, growing, healthy, low-birthweight infant. Very-low-birthweight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously. Similac Special Care with Iron is available in 24 Calories per fluid ounce and contains 1.8 milligrams of iron per 100 Calories. Similac Special Care is available in 20 and 24 Calories per fluid ounce and contains 0.37 milligram of iron per 100 Calories; additional iron may be required.

Caution: Tolerance to enteral feedings should be confirmed by initially offering small volumes of hypocaloric formula followed by cautious progression to higher caloric feedings. At the first signs of intestinal dysfunction (spitting up, abnormal stool, etc.) enteral feeding should be slowed or discontinued.

Similac Natural Care: A low-iron, human milk fortifier with added taurine and L-carnitine. For growing low-birthweight infants. Designed to be mixed with human milk or to use alternately with human milk. Product improves the intake of minerals and vitamins. Similac Natural Care and Similac Special Care 24 have similar compositions, except that Similac Natural Care contains additional calcium and phosphorus. Contains 0.37 milligram of iron per 100 Calories; additional iron may be required.

Caution: This formula is not intended to be fed as the sole source of nutrients. Confirm tolerance to enteral feeding by initially offering small volumes of unfortified human milk. Similac Natural Care can then be added in increasing amounts to human milk as tolerated or as an alternate to human milk. Product is not designed to be fed to infants weighing more than 3,600 grams (7 pounds 14 ounces).

Similac PM (60/40): A nutritionally complete formula with added taurine and L-carnitine. For infants with marginal homeostatic capacity. Also for infants who are predisposed to hypocalcemia or whose renal, digestive, or cardiovascular functions would benefit from lowered mineral levels. Appropriate as an initial feeding for low-birthweight infants; additional calcium, phosphorus, and sodium may be required during periods of rapid growth. Has a 60:40 ratio of whey to casein. Contains 0.22 milligram of iron per 100 Calories; additional iron may be required.

Caution: In conditions where the infant is losing abnormal quantities of one or more electrolytes, it may be necessary to supply electrolytes from sources other than formulas. Also, it may be necessary to supply low-birthweight infants weighing less than 1,500 grams (3 pounds 5 ounces) at birth with additional calcium, phosphorus, and sodium during periods of rapid growth.

Wyeth-Ayerst Laboratories

“Preemie” SMA (20/24 Cal): A nutritionally complete formula with added taurine. For the premature, very-low-birthweight, and low-birthweight infant. Available in 20 and 24 Calories per fluid ounce. “Preemie” SMA 20 contains 0.45 milligram of iron per 100 Calories and “Preemie” SMA 24 contains 0.38 milligram of iron per 100 Calories; additional iron may be required.

Caution: Feedings and progression of feedings should be monitored closely by a qualified health care professional. Once a weight of approximately 2,000 grams (4 pounds 6 ounces) is achieved, the infant should be progressed to a term formula, unless otherwise judged by the pediatrician.

B-2. Exempt Infant Formulas: For Metabolic Disorders

Inherited metabolic disorders are often manifested in the neonatal period. In recent years, these disorders have been successfully managed with the use of medical or dietary therapy when diagnosed and treated early in life. Burton (1987) noted that treatment is worth pursuing when it means the prevention of significant mental retardation or death.

Products with a defined formulation have accelerated the success of dietary treatment of a wide variety of medical conditions. Some formulas may be deficient in one or more specific amino acids. For example, an amino acid may be present at low levels or entirely absent in these formulas. Some formulas may not contain any nitrogen or carbohydrate source. Recently, the industry has introduced to the marketplace metabolic modules. These products contain all essential amino acids, except the disease-restricted amino acid, as well as vitamins and minerals. These products offer still another level of flexibility for the professional providing health care to persons with amino acid metabolism disorders.

Below is a detailed description of exempt infant formulas that are formulated for the dietary treatment of specific inborn errors of metabolism in infants. **These products should not be used for parenteral nutrition.** Where applicable, the caution statement is based on information taken from company literature. **Appendix B-2** provides a quick reference for additional information on these formulas. Formulas designed for children and adults are considered medical foods and are listed beginning on page 24.

Mead Johnson Nutritionals

Lofenalac: A nutritionally incomplete, low-phenylalanine, protein (casein) hydrolysate diet powder with added L-methionine, L-tyrosine, L-tryptophan, L-histidine, taurine, and L-carnitine. It is useful for the dietary management of phenylketonuria (PKU) in newborn infants, older infants, and children. The phenylalanine content is sufficiently low to allow flexibility in adjusting phenylalanine content of the diet to meet the individual phenylketonuric's requirement for growth. Contains 1.88 milligrams of iron per 100 Calories.

Caution: Nutritionist should monitor the total diet of the infant or child with phenylketonuria to assure adequate nutrition and growth. This should also help avoid phenylalanine deficiency due to the use of a low-phenylalanine diet.

Low-Phe/Tyr Diet Powder (Product 3200 AB): A nutritionally incomplete, low-phenylalanine, low-tyrosine diet powder with added L-methionine, L-tryptophan, L-histidine, taurine, and L-carnitine. For the dietary management of certain hereditary tyrosinemias in infants. Fat, carbohydrates, vitamins, and minerals are present in appropriate amounts to completely meet infants' needs. Phenylalanine and tyrosine must be provided in sufficient amounts from other sources. Contains 1.88 milligrams of iron per 100 Calories.

Caution: **USE THIS FORMULA AS A SOLE DIET ONLY UNTIL HIGH PLASMA LEVELS OF TYROSINE RETURN TO NORMAL RANGE.** Certain tyrosinemias may require methionine restriction as well. In these cases, Low-Phe/Tyr Diet Powder is not indicated. Low Phe/Tyr Diet Powder must be used with other foods which provide sufficient levels of phenylalanine and tyrosine to promote growth.

MSUD Diet Powder: A nutritionally incomplete, leucine-, isoleucine-, valine-free diet powder with added taurine and L-carnitine. For the dietary management of maple syrup urine disease in infants and children. May also be helpful with supplementation, for hypervalinemia, methylacetoacetic aciduria, leucine-induced hypoglycemia, and hyperleucine-isoleucinemia. Free amino acids provide the nitrogen. May be used as a sole source of nutrition until plasma levels of leucine, isoleucine, and valine return to normal ranges, after which product must be supplemented with infant formula or milk and/or foods of known composition to provide sufficient branched-chain amino acids to help meet nutritional requirements. Contains 1.88 milligrams of iron per 100 Calories.

Caution: MSUD Diet Powder is to be used for the dietary management of infants and children with maple syrup urine disease or other disorders of branched-chain amino acid metabolism under the direct and continuing supervision of a physician. Appropriate amounts of leucine, isoleucine, and valine must be supplied by other foods. To maintain appropriate restrictions, careful dietary management (including frequent monitoring of plasma amino acid levels and adjustments of intake) is necessary.

Low-Methionine Diet Powder (Product 3200 K): A nutritionally incomplete, soy-based isolate, diet powder with added taurine and L-carnitine, but no added L-methionine. For the dietary management of homocystinuria in infants and children. Contains methionine at 39 milligrams per 100 Calories to meet the methionine requirements. Contains 1.88 milligrams of iron per 100 Calories.

Caution: Plasma levels of amino acids must be monitored in order to properly regulate the overall diet.

Mono- and Disaccharide-Free Diet Powder (Product 3232 A): A nutritionally incomplete protein (casein) hydrolysate formula base with added taurine and L-carnitine. For the dietary management of disaccharidase deficiencies and impaired monosaccharide transport in infants and children under 4 years old. Also used in managing intractable diarrhea in infants. Contains 1.88 milligrams of iron per 100 Calories when prepared with added carbohydrates as described on label.

Caution: Adequate carbohydrate must be supplied.

Protein-Free Diet Powder (Product 80056): A nutritionally incomplete formula base which supplies no protein or amino acids. For use in the dietary management of B12 independent methylmalonic aciduria, propionic aciduria, hyperlysinemia, arginemia urea cycle disorders, histidinemia, and gyrate atrophy in infants. Product provides calories from carbohydrate and fat as well as all essential vitamins and minerals. Contains 2.2 milligrams of iron per 100 calories of dry product.

Caution: Adequate protein, sodium, potassium, and chloride must be supplied. The electrolyte content of the added protein must be taken into account.

Mead Johnson Nutritionals, Distributor

Metabolic Module PKU 1: A nutritionally incomplete, phenylalanine-free modular formula containing a mixture of L-amino acids for persons with phenylketonuria and hyperphenylalaninemia. Metabolic Module PKU is available in three "stages." Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module PKU 1 is for infants and contains 34 milligrams of iron per 100 grams of product. See pages 25 and 26 for information on Module PKU 2 and Module PKU 3.

Caution: METABOLIC MODULE PKU IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and phenylalanine must be included in the diet, along with the appropriate PKU Module. The total daily amount depends on the protein requirement as well as individual phenylalanine tolerance.

Metabolic Module HIST 1: A nutritionally incomplete, histidine-free modular formula containing a mixture of L-amino acids for persons with histidinemia. Metabolic Module HIST is available in two "stages." Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module HIST 1 is for infants and contains 34 milligrams of iron per 100 grams of product. See page 26 for information on Module HIST 2.

Caution: METABOLIC MODULE HIST IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and histidine must be included in the diet, along with the appropriate HIST Module. The total daily amount depends on the protein requirement as well as individual histidine tolerance.

Metabolic Module HOM 1: A nutritionally incomplete, methionine-free modular formula containing a mixture of L-amino acids for persons with homocystinuria due to cystathionine β -synthase deficiency (vitamin B-6-independent form). Metabolic Module HOM is available in two "stages." Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module HOM 1 is for infants and contains 34 milligrams of iron per 100 grams of product. See page 26 for information on Module HOM 2.

Caution: METABOLIC MODULE HOM IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and methionine must be included in the diet, along with the appropriate HOM Module. The total daily amount depends on the protein requirement, as well as individual methionine tolerance.

Metabolic Module LYS 1: A nutritionally incomplete, lysine-free modular formula containing a mixture of L-amino acids for persons with hyperlysinemia due to lysine-ketoglutarate reductase deficiency and persons with saccharopinuria with

hyperlysinemia. Metabolic Module LYS is available in two "stages." Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module LYS 1 is for infants and contains 34 milligrams of iron per 100 grams of product. See page 26 for information on Module LYS 2.

Caution: METABOLIC MODULE LYS IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and lysine must be included in the diet, along with the appropriate LYS Module. The total daily amount depends on the protein requirement, as well as individual lysine tolerance.

Metabolic Module MSUD 1: A nutritionally incomplete, isoleucine-, leucine-, and valine-free modular formula containing a mixture of L-amino acids for persons with maple syrup urine disease (MSUD), hypervalinemia, methylacetoacetic aciduria, ketotic hypoglycemia (leucine-induced), and hyperprolinemia type II, with hyperleucine-isoleucinemia. Metabolic Module MSUD is available in two "stages." Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module MSUD 1 is for infants and contains 34 milligrams of iron per 100 grams of product. See page 27 for information on Module MSUD 2.

Caution: METABOLIC MODULE MSUD IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate and isoleucine, leucine, and valine must be included in the diet, along with the appropriate MSUD Module. The total daily amount depends on the protein requirement as well as individual isoleucine, leucine, and valine tolerances.

Metabolic Module OS 1: A nutritionally incomplete, isoleucine-, methionine-, threonine-, and valine-free product containing a mixture of L-amino acids for persons with propionic acidemia and methylmalonic acidemia. Metabolic Module OS is available in two "stages." Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module OS 1 is for infants and may contain 100 milligrams isoleucine (for technical reasons) and contains 34 milligrams of iron per 100 grams of product. See page 27 for information on Module OS 2.

Caution: METABOLIC MODULE OS IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and isoleucine, threonine, methionine, and valine must be included in the diet, along with the appropriate OS Module. The total daily amount depends on the protein requirement as well as individual isoleucine, threonine, methionine, and valine tolerances.

Metabolic Module TYR 1: A nutritionally incomplete, phenylalanine- and tyrosine-free modular formula containing a mixture of L-amino acids for persons with tyrosinemia type II, due to tyrosine amino-transferase deficiency (Richner-Hanhart Syndrome). Persons with tyrosinosis (tyrosinemia type I) may require methionine restriction as well. The TYR modules contain L-methionine. Metabolic Module TYR is available in two "stages." Each stage contains a specific amino acid distribution and a vitamin/mineral mix which correspond to an age group and related metabolic demands. Module TYR 1 is for infants and contains 34 milligrams of iron per 100 grams of product. See page 28 for information on Module TYR 2.

Caution: METABOLIC MODULE TYR IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, phenylalanine, and tyrosine must be included in the diet, along with the appropriate TYR Module. The total daily amount depends on the protein requirement based on body weight and age as well as individual phenylalanine and tyrosine tolerances. The TYR modules contain methionine and may not be appropriate for persons with tyrosinosis.

Metabolic Module UCD 1: A nutritionally incomplete product containing a mixture of all essential L-amino acids for persons with urea cycle disorders. May be used for hyperammonemia type I, due to carbamoyl phosphate synthetase, hyperammonemia type II, due to ornithine carbamoyl transferase deficiency, citrullinemia, argininosuccinic aciduria, hyperargininemia, and hyperornithinemia. Metabolic Module UCD is available in two "stages." Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module UCD 1 is for infants and contains 40 milligrams of iron per 100 grams of product. See page 28 for information on Module UCD 2.

Caution: METABOLIC MODULE UCD IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and magnesium must be included in the diet, along with the appropriate UCD Module. The total daily amount depends on amino acid tolerances.

Ross Laboratories, Distributor

Analog XP: A nutritionally incomplete, phenylalanine-free, amino acid-modified formula with added L-glutamine, L-tyrosine, chromium, molybdenum, selenium taurine and L-carnitine. For infants with phenylketonuria (PKU). Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 7 milligrams of iron per 100 grams of product.

Caution: THIS FORMULA MUST BE GIVEN ONLY TO INFANTS WITH PROVEN PHENYLKETONURIA (PKU) WHO ARE UNDER STRICT MEDICAL SUPERVISION. Diet must be supplemented with complete protein, fluid, and other nutrients in prescribed quantities to supply the phenylalanine, water, and general nutrient requirements of the infant.

Analog MSUD: A nutritionally incomplete, isoleucine-, leucine-, valine-free amino acid-modified formula with added chromium, molybdenum, selenium, taurine and L-carnitine. For infants with maple syrup urine disease. Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 7 milligrams of iron per 100 grams of product.

Caution: THIS FORMULA MUST BE GIVEN ONLY TO INFANTS WITH PROVEN MAPLE SYRUP URINE DISEASE WHO ARE UNDER STRICT MEDICAL SUPERVISION. Diet must be supplemented with complete protein, fluid, and other nutrients in prescribed quantities to supply the branched-chain amino acids, water, and general nutrient requirements of the infant.

Analog XLYS,TRY: A nutritionally incomplete lysine- and tryptophan-free, amino acid-modified infant formula with added chromium, molybdenum, selenium, taurine and L-carnitine. For infants with glutaric aciduria type I. Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 7 milligrams of iron per 100 grams of product.

Caution: THIS FORMULA MUST BE GIVEN ONLY TO INFANTS WITH PROVEN GLUTARIC ACIDURIA TYPE I WHO ARE UNDER STRICT MEDICAL SUPERVISION. Diet must be supplemented with complete protein, fluid, and other nutrients in prescribed quantities to supply the lysine, tryptophan, water, and general nutrient requirements of the infant.

Analog XMET: A nutritionally incomplete, methionine-free, amino acid-modified infant formula with added chromium, molybdenum, selenium, taurine and L-carnitine. For infants with vitamin B-6 nonresponsive homocystinuria or hypermethioninemia. Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 7 milligrams of iron per 100 grams of product.

Caution: THIS FORMULA MUST BE GIVEN ONLY TO INFANTS WITH PROVEN VITAMIN B-6 NONRESPONSIVE HOMOCYSTINURIA OR HYPERMETHIONINEMIA WHO ARE UNDER STRICT MEDICAL SUPERVISION. Diet must be supplemented with complete protein, fluid, and other nutrients in prescribed quantities to supply the methionine, water, and general nutrient requirements of the infant.

Analog XPHEN, TYR: A nutritionally incomplete, phenylalanine- and tyrosine-free, amino acid-modified formula with added chromium, molybdenum, selenium, taurine and L-carnitine. For infants with tyrosinemia. Caloric density, osmolality, and iron

content depend on the prescribed quantity. Contains 7 milligrams of iron per 100 grams of product.

Caution: THIS FORMULA MUST BE GIVEN ONLY TO INFANTS WITH PROVEN TYROSINEMIA WHO ARE UNDER STRICT MEDICAL SUPERVISION. Diet must be supplemented with complete protein, fluid, and other nutrients in prescribed quantities to supply the phenylalanine, tyrosine, water, and general nutrient requirements of the infant.

Analog XPHEN, TYR, MET: A nutritionally incomplete phenylalanine-, tyrosine- and methionine-free formula with added chromium, molybdenum, selenium, taurine and L-carnitine. For infants with tyrosinemia type I. Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 7 milligrams of iron per 100 grams of product.

Caution: THIS FORMULA MUST BE GIVEN ONLY TO INFANTS WITH PROVEN TYROSINEMIA TYPE I WHO ARE UNDER STRICT MEDICAL SUPERVISION. Diet must be supplemented with complete protein, fluid, and other nutrients in prescribed quantities to supply the phenylalanine, tyrosine, methionine, water, and general nutrient requirements of the infant.

Analog XMET, THRE, VAL, ISOLEU: A nutritionally incomplete, methionine-, threonine-, and valine-free, low-isoleucine formula with added taurine and L-carnitine. For infants with methylmalonic or propionic acidemia. Fortified with chromium, molybdenum, and selenium. Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 7 milligrams iron per gram of product.

Caution: THIS FORMULA MUST BE GIVEN ONLY TO INFANTS WITH PROVEN METHYLMALONIC OR PROPIONIC ACIDEMIA WHO ARE UNDER STRICT MEDICAL SUPERVISION. Diet must be supplemented with complete protein, fluid, and other nutrients in prescribed quantities to supply the methionine, threonine, valine, isoleucine, water, and general nutrient requirements of the infant.

B-3. Exempt Infant Formulas: For Unusual Medical or Dietary Problems

In addition to formulas for the low-birthweight infant and the infant with inborn errors of metabolism, exempt infant formulas have been designed to meet other special individualized needs. Often nutrition management is the important factor, and when implemented, provides nutrients in proper amounts and/or forms to permit the infant to achieve an optimal growth rate approaching the individual's potential. Characteristics of these formulas may include, but are not limited to, the following:

- hypercaloric to meet increased energy requirements in a limited volume;
- low electrolytes for renal disorders;
- protein hydrolysates for protein malabsorption disorders and/or food allergies;
- modified fat for fat malabsorption disorders; and
- an alternate carbohydrate source for infants with monosaccharide and disaccharide deficiencies.

Below is a detailed description of exempt infant formulas for unusual medical or dietary problems. **These products should not be used for parenteral nutrition.** Where applicable, the caution statement is based on information taken from company literature. **Appendix B-3** provides a quick reference for additional information on each formula.

Mead Johnson Nutritionals

Nutramigen: A nutritionally complete, lactose-free, protein (casein) hydrolysate formula with added L-cystine, L-tyrosine, L-tryptophan, taurine, and L-carnitine for oral or tube feedings. For infants and children sensitive to intact proteins of milk and other foods. Appropriate for feeding infants with severe or multiple food allergies, colic, persistent diarrhea, or other gastrointestinal disturbances, or galactosemia. May be continued as a milk substitute in the diets of children and adults with severe and multiple food allergies or intolerances. Contains 1.88 milligrams of iron per 100 Calories.

Pregestimil: A nutritionally complete, lactose-free, protein (casein) hydrolysate formula with MCT oil and added L-cystine, L-tyrosine, L-tryptophan, taurine, and L-carnitine. For infants with impaired fat absorption or sensitive to intact proteins of milk and other foods. Appropriate for infants with a variety of conditions, including severe or intractable diarrhea, food allergies, colic, disaccharidase deficiency, malabsorption due to dysfunction, steatorrhea, cystic fibrosis and severe protein-calorie malnutrition. May be continued as a milk substitute in the diets of children and adults with severe and multiple food allergies or intolerances. Contains 1.88 milligrams of iron per 100 Calories.

Portagen: A nutritionally complete, casein-based, powdered formula with medium-chain triglycerides and added taurine and L-carnitine. For infants, children, and adults who do not efficiently digest conventional food fat or absorb the resulting long-chain fatty acids. Contains 1.88 milligrams of iron per 100 Calories.

Caution: The usual intake of water should be maintained when Portagen is used as the sole source of nutrition or major part of the diet.

Ross Laboratories

Alimentum Protein Hydrolysate Formula with Iron: A nutritionally complete, lactose-free, corn-free, MCT oil-containing, glucose-low, fructose-low protein (casein) hydrolysate formula with added taurine and L-carnitine. For infants sensitive to cow's milk, other intact protein, or pancreatic insufficiency. Also appropriate for infants with chronic diarrhea, multiple food allergies, acute and chronic protein-energy malnutrition, galactosemia, and carbohydrate or fat malabsorption. Contains 1.8 milligrams of iron per 100 Calories.

Calcilo XD: A nutritionally incomplete, vitamin D-free, low-calcium formula with added taurine and L-carnitine. For the dietary management of infants with hypercalcemia. Contains less than 10 milligrams calcium per 100 Calories. Contains 1.1 milligrams iron per 100 Calories; additional iron may be required.

Caution: THIS FORMULA MUST BE GIVEN ONLY TO INFANTS WHOSE CALCIUM AND/OR VITAMIN D INTAKES MUST BE SEVERELY RESTRICTED, AS IN HYPERCALCEMIA, AND WHO ARE UNDER STRICT MEDICAL SUPERVISION. Calcium and vitamin D requirements should be determined by appropriate laboratory tests. This formula does not supply the minimum recommended intake of calcium or vitamin D for normal infants. Use only as directed.

ProViMin: A nutritionally incomplete protein base containing only a blend of casein, minerals, and vitamins, with added taurine and L-carnitine. Use in liquid diets of infants and children with chronic diarrhea and other malabsorptive disorders that require restriction of amounts and types of fat and carbohydrate. Contains 6.7 milligrams of iron per 100 Calories of powder; additional iron may be required.

Caution: This product does not supply sufficient carbohydrate or sufficient fat or linoleic acid for infants and children. These nutrients should be supplied from other sources under the supervision of a physician. Additional iron and vitamin D may be necessary.

RCF: A nutritionally incomplete, carbohydrate-free, soy-formula base with added taurine, L-methionine, and L-carnitine. For persons unable to tolerate the types or amounts of carbohydrates in milk or conventional infant formulas. May be used in cases of intractable diarrhea. Allows physician to prescribe type and amount of carbohydrate (sucrose, dextrose powder, or Polycose glucose polymers powder.) Contains 0.22 milligram of iron per 100 Calories when reconstituted with carbohydrate; additional iron may be required.

Caution: CARBOHYDRATES MUST BE ADDED BEFORE FEEDING. Use RCF only under the supervision of a physician who provides instruction on the amount and type of carbohydrate and the amount of water to be added.

Wyeth-Ayerst Laboratories

S-14: A nutritionally incomplete, milk-based, low-leucine product with added taurine. For infants with leucine-sensitive hypoglycemia. Contains 1.8 milligrams of iron per 100 Calories.

Caution: THIS FORMULA IS NOT FOR GENERAL FEEDING. USE ONLY UNDER THE SUPERVISION OF THE ATTENDING PHYSICIAN. Infants receiving this formula need to be monitored closely and the details of formula use and preparation should be followed carefully.

S-29: A nutritionally incomplete formula with added taurine. For infants who need a formula with an exceptionally low renal solute load. Appropriate for renal acidosis with hyperphosphatemia, pseudohypo-parathyroidism, diabetes insipidus, hypercalcemia, and severe cardiac decompensation. The mineral content is not sufficient to support normal growth and development. In prolonged use, blood and urine electrolytes should be carefully monitored. Dietary calcium and other supplements may be required. Contains 1.9 milligrams of iron per 100 Calories.

Caution: THIS FORMULA IS NOT FOR GENERAL FEEDING. USE ONLY UNDER THE SUPERVISION OF THE ATTENDING PHYSICIAN. Infants receiving this formula need to be monitored closely and the details of formula use and preparation should be followed carefully.

S-44: A nutritionally incomplete formula with added taurine and containing no added vitamins. For infants who need a formula with an exceptionally low renal solute load and who have idiopathic hypercalcemia or hypervitaminosis D. Contains 1.9 milligrams of iron per 100 Calories.

Caution: THIS FORMULA IS NOT FOR GENERAL FEEDING. USE ONLY UNDER THE SUPERVISION OF THE ATTENDING PHYSICIAN. Infants receiving this formula need to be monitored closely and the details of formula use and preparation should be followed carefully.

C. Medical Foods

In addition to the infant formulas and exempt infant formulas, special formulas are available to meet the specific needs of children over 1 year of age and adults. These products, generally called medical foods, have been designed for metabolic disorders, inborn errors of amino acid metabolism, malabsorption syndrome, allergies, electrolytic imbalances, and other conditions that may be found in or may continue in the older child or adult.

According to FDA's 1983 working definition (Hattan and MacKey, 1989), a food may be classified as a medical food if it:

- is a food for oral or tube feeding;
- makes a preventive claim or a therapeutic claim, or both;
- provides all or a major part of the total daily nutrient needs of the person; and
- must be used under medical supervision.

Medical foods may be classified as follows:

- **Nutritionally Complete:** Products that contain all nutrients necessary to support the growth of an individual.
- **Nutritionally Incomplete:** Products that consist of a single or mixed nutrient source that cannot support growth of an individual.
- **Formulas for Metabolic Disorders:** These formulas are covered under the Exempt Infant Formula Act when indicated for infants use. However, when labeled for use by children and adults, these products become medical foods.
- **Oral Rehydration Solutions:** Electrolyte solutions used to treat moderate to severe diarrhea.

Medical foods are usually lactose-free to avoid lactose intolerance and may be modifications of infant formulas. They may contain qualitative and/or quantitative modifications of fat, carbohydrate, and protein or they may be free of carbohydrate, protein, or fat. Some may contain Medium-Chain Triglycerides (MCT) and may be administered orally or by tube feeding. **If feeding by tube, none of the formulas are to be fed parenterally, that is, via a peripheral or central venous catheter. Where tube feeding is indicated, this type of enteral feeding must be administered through the gastrointestinal tract.**

Generally, vitamin and mineral levels are in amounts that are comparable to those in standard adult formulas. For several medical foods, levels of minerals or vitamins are not sufficient to support normal growth; supplementation may be necessary. **Note caution statements.** These products may or may not be iron-fortified.

For many medical foods, manufacturers recommend direct medical supervision. Close supervision is necessary so that the diet can be adjusted periodically to meet the needs of the individual (Committee on Nutrition, 1985). When used with infants and young children, the total caloric and nutrient intake must be monitored and appropriate adjustments made to help assure normal growth and development. Many medical foods are hyperosmolar; therefore, these products may need to be diluted on initial

introduction and gradually increased in strength and volume based on tolerance. Some medical foods are so hyperosmolar that their use with infants, especially neonates, should be undertaken only under direct medical supervision. When used as a sole source of nutrients over a prolonged period of time for these groups, the nutritional status should be monitored. Hematological, biochemical, and developmental testing should be carefully performed because of the possible continuing nutrient losses secondary to disease and the demands of growth (Committee on Nutrition, 1985).

Several categories of medical foods are discussed below--diets for metabolic disorders, complete special diets, complete elemental diets, and incomplete modular diets. **These products should not be used for parenteral nutrition.** Where applicable, the caution statement is based on information taken from company literature. **Appendixes C-1 through C-4** provide quick references for additional information for these products in the order as discussed in this section.

C-1. Medical Foods: Diets for Metabolic Disorders

(Also see general information presented in section B-2, page 12)

Below is a detailed description of diets for metabolic disorders. **These products should not be used for parenteral nutrition.** Where applicable, the caution statement is based on information taken from company literature. **Appendix C-1** provides a quick reference for additional information on these products.

Kendall McGaw Laboratories, Inc.

Amin-Aid: A nutritionally incomplete, essential amino acid and calorie supplement for oral or tube feeding. For the dietary management of persons with acute or chronic renal failure. It contains minimal electrolytes. Amin-Aid may be used as the principal dietary source of nitrogen or may be used for the addition of essential amino acids, histidine, and calories to the diet. It contains no iron.

Caution: USE THIS PRODUCT ONLY UNDER MEDICAL SUPERVISION. IT SHOULD NOT BE FED TO PERSONS WITH INBORN ERRORS OF AMINO ACID METABOLISM. Persons on prolonged use of this product should be monitored. For osmotically-sensitive individuals, Amin-Aid may be administered slowly or diluted to one-half or three-quarters strength to reduce osmolality. All persons receiving Amin-Aid as the principal source of nutrition should receive vitamin and mineral supplements. Use with children or pregnant and lactating women has not been studied.

Hepatic-Aid II: A nutritionally incomplete, vitamin-free, amino acid and calorie supplement for oral or tube feeding. For the dietary management of persons with chronic liver disease. Has no added phenylalanine or aspartic acid. Contains elevated levels of branched-chain amino acids and arginine and low levels of aromatic amino acids and methionine. Contains no iron.

Caution: USE THIS PRODUCT ONLY UNDER MEDICAL SUPERVISION. HEPATIC-AID II SHOULD NOT BE FED TO PERSONS WITH INBORN ERRORS OF AMINO ACID METABOLISM. This product has not been tested with persons who have severe encephalopathy or frank hepatic coma. Blood ammonia should be monitored frequently in persons with liver disease. Persons on prolonged use of this product should be monitored. For osmotically-sensitive individuals, Hepatic-Aid II may be administered slowly or diluted to one-half or three-quarters strength to reduce osmolality. Contains a negligible quantity of electrolytes and no vitamins. These must be supplemented if Hepatic-Aid II constitutes the primary source of amino acids and calories. Use with children or pregnant and lactating women has not been studied.

Mead Johnson Nutritionals

Phenyl-Free: A nutritionally incomplete, phenylalanine-free diet powder. For the dietary management of phenylketonuria (PKU) in children and adults. Free amino acids supply the nitrogen. Product should be consumed along with foods containing phenylalanine in the prescribed diet to assure optimal protein utilization. The combination also provides needed calories while meeting restricted phenylalanine requirements. The vitamin and mineral levels have been established to complement the remainder of the diet considering a wide variety of individuals. Phenyl-Free supplies less calories per gram of protein than Lofenalac. Contains 3 milligrams of iron per 100 Calories.

Caution: THIS PRODUCT SHOULD NOT BE USED AS A SOLE SOURCE OF NUTRITION. Care must be taken to choose foods that will provide sufficient additional phenylalanine and adequate nourishment to properly support growth and development. A physician should frequently and carefully supervise the use of Phenyl-Free and periodically adjust the diet on the basis of frequent blood and urine tests. Effectiveness of the product in low phenylalanine dietary management of maternal PKU has not been clinically determined.

Metabolic Module PKU 2: A nutritionally incomplete, phenylalanine-free modular formula containing a mixture of L-amino acids. For persons with phenylketonuria and hyperphenylalaninemia. Metabolic Module PKU is available in three "stages." Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module PKU 2 is for children and contains 15 milligrams of iron per 100 grams of product. See page 15 for information on Module PKU 1.

Caution: METABOLIC MODULE PKU IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and phenylalanine must be included in the diet, along with the appropriate PKU Module. The total daily amount depends on the protein requirement as well as individual phenylalanine tolerance.

Metabolic Module PKU 3: A nutritionally incomplete, phenylalanine-free modular formula containing a mixture of L-amino acids. For persons with phenylketonuria and hyperphenylalaninemia. Metabolic Module PKU is available in three “stages.” Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module PKU 3 is for adolescents and pregnant women and contains 21 milligrams of iron per 100 grams of product. See page 15 for information on Module PKU 1.

Caution: METABOLIC MODULE PKU IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and phenylalanine must be included in the diet, along with the appropriate PKU metabolic Module. The total daily amount depends on the protein requirement as well as individual phenylalanine tolerance.

Metabolic Module HIST 2: A nutritionally incomplete, histidine-free modular formula containing a mixture of L-amino acids. For persons with histidinemia. Metabolic Module HIST is available in two “stages.” Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module HIST 2 is for children and contains 15 milligrams of iron per 100 grams of product. See page 15 for information on Module HIST 1.

Caution: METABOLIC MODULE HIST IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and histidine must be included in the diet, along with the appropriate HIST Module. The total daily amount depends on the protein requirement as well as individual histidine tolerance.

Metabolic Module HOM 2: A nutritionally incomplete, methionine-free modular formula containing a mixture of L-amino acids. For persons with homocystinuria due to cystathionine β -synthase deficiency (vitamin B-6-independent form). Metabolic Module HOM is available in two “stages.” Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module HOM 2 is for children and contains 15 milligrams of iron per 100 grams of product. See page 15 for information on Module HOM 1.

Caution: METABOLIC MODULE HOM IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and methionine must be included in the diet, along with the appropriate HOM Module. The total daily amount depends on the protein requirement as well as individual methionine tolerance.

Metabolic Module LYS 2: A nutritionally incomplete, lysine-free modular formula containing a mixture of L-amino acids. For persons with hyperlysinemia due to lysine-ketoglutarate reductase deficiency and persons with saccharopinuria with hyperlysinemia. Metabolic Module LYS is available in two “stages.” Each stage

contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module LYS 2 is for children and contains 15 milligrams of iron per 100 grams of product. See page 15 for information on Module LYS 1.

Caution: METABOLIC MODULE LYS IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and lysine must be included in the diet, along with the appropriate LYS Module. The total daily amount depends on the protein requirement as well as individual lysine tolerance.

Metabolic Module MSUD 2: A nutritionally incomplete, isoleucine-, leucine-, and valine-free modular formula containing a mixture of L-amino acids. For persons with maple syrup urine disease (MSUD), hypervalinemia, methylacetoacetic aciduria, ketotic hypoglycemia (leucine-induced), and hyperprolinemia type II, with hyperleucine-isoleucinemia. Metabolic Module MSUD is available in two “stages.” Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module MSUD 2 is for children and contains 15 milligrams of iron per 100 grams of product. See page 16 for information on Module MSUD 1.

Caution: METABOLIC MODULE MSUD IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and isoleucine, leucine, and valine must be included in the diet, along with the appropriate MSUD Module. The total daily amount depends on the protein requirement, as well as individual isoleucine, leucine, and valine tolerances.

Metabolic Module OS 2: A nutritionally incomplete, isoleucine-, methionine-, threonine-, and valine-free modular formula containing a mixture of L-amino acids. For persons with propionic acidemia and methylmalonic acidemia. Metabolic Module OS is available in two “stages.” Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module OS 2 is for children and may contain 150 milligrams isoleucine (for technical reasons) and contains 15 milligrams of iron per 100 grams of product. See page 16 for information on Module OS 1.

Caution: METABOLIC MODULE OS IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and isoleucine, threonine, methionine, and valine must be included in the diet, along with the appropriate OS Module. The total daily amount depends on the protein requirement as well as individual isoleucine, threonine, methionine, and valine tolerances.

Metabolic Module TYR 2: A nutritionally incomplete, phenylalanine- and tyrosine-free modular formula containing a mixture of L-amino acids. For persons with tyrosinemia type II, due to tyrosine amino-transferase deficiency (Richner-Hanhart Syndrome). Persons with tyrosinosis (tyrosinemia type I) may require methionine restriction as well. The TYR Modules contain methionine. Metabolic Module TYR is available in two “stages.” Each stage contains a specific amino acid distribution and a vitamin/mineral mix which correspond to an age group and related metabolic demands. Module TYR 2 is for children and contains 15 milligrams of iron per 100 grams of product. See page 17 for information on Module TYR 1.

Caution: METABOLIC MODULE TYR IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, phenylalanine, and tyrosine must be included in the diet, along with the appropriate TYR Module. The total daily amount depends on the protein requirement as well as individual phenylalanine and tyrosine tolerances. The TYR modules contain methionine and may not be appropriate for persons with tyrosinosis.

Metabolic Module UCD 2: A nutritionally incomplete product containing a mixture of all essential L-amino acids, for persons with urea cycle disorders. May be used for hyperammonemia type I due to carbamoyl phosphate synthetase, hyperammonemia type II due to ornithine carbamoyl transferase deficiency, citrullinemia, arginino-succinic aciduria, hyperargininemia, and hyperornithinemia. Metabolic Module UCD is available in two “stages.” Each stage contains a specific amino acid distribution and vitamin/mineral mix which correspond to an age group and related metabolic demands. Module UCD 2 is for children and contains 15 milligrams of iron per 100 grams of product. See page 17 for information on Module UCD 1.

Caution: METABOLIC MODULE UCD IS NOT A COMPLETE FOOD AND IS TO BE USED ONLY UNDER THE SUPERVISION OF A PHYSICIAN. Adequate amounts of fat, carbohydrate, and magnesium must be included in the diet, along with the appropriate UCD Module. The total daily amount depends on amino acid tolerances.

Ross Laboratories

Maxamaid XP: A nutritionally incomplete, phenylalanine-free, fat-free medical food with added L-tyrosine. For the dietary management of phenylketonuria (PKU) in children 1 to 8 years old. Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 12 milligrams of iron per 100 grams of product.

Caution: THIS PRODUCT IS FOR PERSONS WITH PROVEN PHENYLKETONURIA WHO ARE UNDER STRICT MEDICAL SUPERVISION. NOT INTENDED FOR INFANTS UNDER 1 YEAR OLD. Diet must be supplemented with natural protein, fluid, and other nutrients in prescribed quantities to supply the phenylalanine, water, and general nutrition requirements of the individual.

Maxamum XP: A nutritionally incomplete, phenylalanine-free, fat-free medical food with added taurine, L-carnitine, chromium, selenium, and molybdenum. For the dietary management of phenylketonuria (PKU) in children age 8 and older, women in the childbearing years, and other adults. Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 23.5 milligrams of iron per 100 grams of product.

Caution: THIS PRODUCT IS FOR PERSONS WITH PROVEN PHENYLKETONURIA WHO ARE UNDER STRICT MEDICAL SUPERVISION. IT IS NOT INTENDED FOR INFANTS OR CHILDREN UNDER AGE 8. Diet must be supplemented with natural protein, fluid, and other nutrients in prescribed quantities to supply the phenylalanine, water, and general nutrition requirements of the individual.

Maxamaid MSUD: A nutritionally incomplete, isoleucine-, leucine- and valine-free, fat-free medical food. For the dietary management of maple syrup urine disease (MSUD) in children 1 to 8 years old. Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 12 milligrams of iron per 100 grams of product.

Caution: THIS PRODUCT IS FOR PERSONS WITH PROVEN MSUD WHO ARE UNDER STRICT MEDICAL SUPERVISION. IT IS NOT INTENDED FOR INFANTS UNDER 1 YEAR OLD. Diet must be supplemented with natural protein, fluid, and other nutrients in prescribed quantities to supply isoleucine, leucine, valine, water, and general nutrition requirements of the individual.

Maxamum MSUD: A nutritionally incomplete, isoleucine-, leucine-, valine-free, fat-free medical food with added chromium, selenium, molybdenum, taurine, and L-carnitine. For the dietary management of maple syrup urine disease (MSUD) in children age 8 and older, women in the childbearing years, and other adults. Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 23.5 milligrams iron per 100 grams of product.

Caution: THIS PRODUCT IS FOR PERSONS WITH PROVEN MSUD WHO ARE UNDER STRICT MEDICAL SUPERVISION. IT IS NOT INTENDED FOR CHILDREN UNDER 8 YEARS OLD. Diet must be supplemented with natural protein, fluid, and other nutrients in prescribed quantities to supply the isoleucine, leucine, valine, water, and general nutrition requirements of the individual.

Maxamaid XMET: A nutritionally incomplete, methionine-free, fat-free medical food. For the dietary management of vitamin B-6 nonresponsive homocystinuria due to cystathionine- β -synthase deficiency or hypermethioninemia in children age 1 and older and adults. Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 12 milligrams of iron per 100 grams of product.

Caution: THIS PRODUCT IS FOR PERSONS WITH PROVEN HOMOCYSTINURIA OR HYPERMETHIONINEMIA WHO ARE UNDER STRICT MEDICAL SUPERVISION. IT IS NOT INTENDED FOR INFANTS UNDER 1 YEAR OLD. Diet must be supplemented with natural protein, fluid, and other nutrients in prescribed quantities to supply the methionine, water, and general nutritional requirements of the individual.

Maxamaid XPHEN, TYR: Phenylalanine- and tyrosine-free, fat-free medical food. For the dietary management of tyrosinemia in children 1 to 8 years old. Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 12 milligrams of iron per 100 grams of product.

Caution: THIS PRODUCT IS FOR PERSONS WITH PROVEN TYROSINEMIA WHO ARE UNDER STRICT MEDICAL SUPERVISION. IT IS NOT INTENDED FOR INFANTS UNDER 1 YEAR OLD. Diet must be supplemented with natural protein, fluid, and other nutrients in prescribed quantities to supply tyrosine, phenylalanine, water, and general nutrition requirements of the individual.

Maxamaid XMET, THRE, VAL, ISOLEU: Methionine-, threonine-, and valine-free, low isoleucine, fat-free medical food. For the dietary management of methylmalonic acidemia or propionic acidemia in children 1 to 8 years old. Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 12 milligrams of iron per 100 grams of product.

Caution: THIS PRODUCT IS FOR PERSONS WITH PROVEN METHYLMALONIC ACIDEMIA OR PROPIONIC ACIDEMIA WHO ARE UNDER STRICT MEDICAL SUPERVISION. IT IS NOT INTENDED FOR INFANTS UNDER 1 YEAR OLD. Diet must be supplemented with natural protein, fluid, and other nutrients in prescribed quantities to supply the methionine, threonine, valine, isoleucine, water, and general nutrition requirements of the individual.

Maxamaid XLYS, TRY: Lysine- and tryptophan-free, fat-free medical food. For the dietary management of glutaric aciduria type I in children 1 to 19 years old. Caloric density, osmolality, and iron content depend on the prescribed quantity. Contains 12 milligrams of iron per 100 grams of product.

Caution: THIS PRODUCT IS FOR PERSONS WITH PROVEN GLUTARIC ACIDURIA TYPE I WHO ARE UNDER STRICT MEDICAL SUPERVISION. IT IS NOT INTENDED FOR INFANTS UNDER 1 YEAR OLD. Diet must be supplemented with natural protein, fluid, and other nutrients in prescribed quantities to supply lysine, tryptophan, water, and general nutrition requirements of the individual.

C-2. Medical Foods: Complete Special Diets

Below is a detailed description on complete special diets. **These products should not be used for parenteral nutrition.** Where applicable, the caution statement is based on information taken from company literature. **Appendix C-2** provides a quick reference for additional information on these products. (For more information, see section B-3, Exempt Infant Formulas: For Unusual Medical or Dietary Problems, page 19.)

Mead Johnson Nutritionals

Sustacal Liquid: A nutritionally complete, lactose-free, low-residue, fiber-free liquid food for oral or tube feeding. Useful for adults and children age 4 and older requiring general supplementation or with increased nutritional needs. Sustacal pudding is also available with a slightly different formulation than the liquid form. Contains 1.67 milligrams of iron per 100 Calories.

Caution: When used for tube feedings, dilute Sustacal Liquid to half strength initially, and gradually increase to full strength. When used as the sole source of diet, additional water may be required to provide an adequate daily intake of fluids. The electrolyte content should be taken into consideration when this product is used for cardiac persons or those with compromised renal function and fluid balance problems.

Sustacal with Fiber: A nutritionally complete, lactose-free liquid food with added soy polysaccharide fiber for oral or tube feeding. Useful for adults and children age 4 and older requiring dietary fiber or when bulk is needed to maintain bowel regularity. For persons unable to tolerate low-residue feedings; may be used by persons on sodium-restricted diets. Contains 1.2 milligrams of iron per 100 calories.

Caution: When used for tube feedings, dilute Sustacal with Fiber to half strength initially, and gradually increase to full strength. When used as the sole source of diet, additional water may be required to provide an adequate daily intake of fluids; this is particularly true in unconscious or semiconscious persons fed via tube. The electrolyte content should be taken into consideration when the product is used for cardiac persons or those with compromised renal function and fluid balance problems.

Sustacal HC: A nutritionally complete, lactose-free, high-calorie liquid food for oral or tube feeding. Useful for adults and children age 4 and older needing concentrated calories, protein, and other nutrients in a limited volume. Contains 1.0 milligram of iron per 100 Calories.

Caution: When used for tube feedings, dilute Sustacal HC to half strength initially and gradually increase to full strength. Additional water should be given as needed to meet the person's requirements. This is very important for unconscious or semiconscious persons or those with compromised renal function or increased fluid needs.

Sustagen: A high-calorie, high-protein, low-residue nutritional supplement for oral or tube feeding. Useful for adults and children age 4 and older with increased nutritional requirements or as a replacement for solid foods. Suitable for low-fat diets. Contains 1.0 milligram of iron per 100 Calories.

Caution: When used for tube feedings, it is advisable to dilute Sustagen initially, and gradually increase the quantity and concentration. Some persons maintained on Sustagen for a long period of time (many months or years) may develop symptoms associated with an inadequate intake of essential fatty acids because of the relatively low level of fat. Diet should be supplemented, daily, with one tablespoon of corn, soy, sunflower or safflower oil to meet essential fatty acid requirement. When Sustagen is used as the sole food, additional water should be given as required to provide an adequate daily intake of fluids. This is very important for unconscious or semiconscious persons receiving Sustagen by tube.

Isocal: A nutritionally complete, isotonic, lactose-free, low-residue, fiber-free liquid food for oral and tube feeding. For adults and children age 4 and older when voluntary food intake is absent or inadequate to meet nutrient needs; may be used by persons on sodium-restricted diets. Contains 0.9 milligram of iron per 100 Calories.

Caution: When used for tube feedings, Isocal can be initiated at full strength. However, in some cases it is advisable to feed less than full caloric requirements on the first day. Additional water should be given as needed to meet the person's requirements. This is very important for unconscious or semiconscious persons or those with compromised renal function or increased fluid needs.

Isocal HCN: A nutritionally complete, high-calorie, high-nitrogen, low-sodium, lactose-free liquid food for oral or tube feeding. For adults and children age 4 and older who are fluid- and volume-restricted or hypermetabolic. Contains 0.91 milligram of iron per 100 Calories.

Caution: When used for tube feedings, dilute Isocal HCN to half strength initially, and gradually increase to full strength. Additional water should be given as needed to meet the person's requirements. This is very important for unconscious or semiconscious persons or those with compromised renal function or increased fluid needs.

Isocal HN: A nutritionally complete, isotonic, high-nitrogen, lactose-free, low-residue liquid food for oral or tube feeding. Useful for adults and children age 4 and older with increased protein needs; may be used by persons on sodium-restricted diets. Contains 1.44 milligrams of iron per 100 Calories.

Caution: When used for tube feedings, Isocal HN can be initiated at full strength. However, in some cases it is advisable to feed less than full caloric requirements on the first day. Additional water should be given as needed to meet the person's requirements. This is very important for unconscious or semiconscious persons or those with compromised renal function or increased fluid needs.

Lonalac: A nutritionally complete, low-sodium, high-protein food. Useful for toxemia of pregnancy, congestive heart failure, hypertension, nephrosis, hepatic cirrhosis with ascites, and ACTH or cortisone therapy. It contains no iron.

Caution: Lonalac provides only 38 milligrams of sodium per quart. Sodium requirements must be supplied from other sources.

TraumaCal: A nutritionally complete, high nitrogen liquid food for oral and tube feeding. For adults and children age 4 and older. Useful for persons who are metabolically stressed or have chronic obstructive pulmonary disease. Contains 0.59 milligram of iron per 100 Calories.

Caution: When used for tube feedings, dilute TraumaCal to half strength initially, and gradually increase to full strength. Additional water should be given as needed to meet the person's requirements. This is very important for unconscious or semiconscious persons or those with compromised renal function or increased fluid needs.

Ross Laboratories

Enrich: A nutritionally complete, high-fiber, lactose-free liquid food with added soy polysaccharide fiber for oral or tube feeding. For adults and children age 4 and older requiring dietary bulk as well as other nutrients. Useful for persons with intolerance to low-residue feedings (i.e., diarrhea or constipation). Fiber level helps maintain normal bowel function. Contains 1.2 milligrams of iron per 100 Calories.

Caution: THIS PRODUCT IS NOT RECOMMENDED WHEN A LOW-RESIDUE FEEDING IS REQUIRED. When used for tube feedings, follow the physician's instructions. Additional fluid requirements should be met by giving water with or after feedings.

Ensure: A nutritionally complete, lactose-free, low-residue liquid food for oral or tube feeding. For adults and children age 4 and older. Useful when the medical, surgical, or psychological state precludes normal food intake or leads to inadequate nutrition. Sustacal pudding is also available with a slightly different formulation than the liquid form. Contains 0.90 milligram of iron per 100 Calories.

Caution: When used for tube feedings, follow the physician's instructions. Additional fluid requirements should be met by giving water with or after feedings.

Ensure Plus: A nutritionally complete, lactose-free, high-calorie liquid food for oral or tube feeding. For adults and children age 4 and older. Useful when extra calories and correspondingly higher concentrations of protein and most other nutrients are needed to achieve a required caloric intake in a limited volume. Contains 0.85 milligram of iron per 100 Calories.

Caution: When used for tube feedings, follow the physician's instructions. Additional fluid requirement should be met by giving water with or after feedings.

Ensure HN: A nutritionally complete, lactose-free, high-nitrogen, low-residue liquid food for oral or tube feeding. For adults and children age 4 and older with increased protein needs. Contains 1.29 milligrams of iron per 100 Calories.

Caution: When used for tube feedings, follow the physician's instructions. Additional fluid requirements should be met by giving water with or after feedings.

Ensure Plus HN: A nutritionally complete, lactose-free, high-calorie, high-nitrogen liquid food for oral or tube feeding. For adults and children age 4 and older with increased caloric and protein needs or limited volume intake. Contains 1.27 milligrams of iron per 100 Calories.

Caution: When used for tube feedings, follow the physician's instructions. Additional fluid requirements should be met by giving water with or after feedings.

Glucerna: A nutritionally complete, low-carbohydrate, high-fat, gluten- and lactose-free liquid food with added soy fiber, chromium, selenium, molybdenum, taurine, and L-carnitine for oral or tube feeding. For adults and children 4 years of age and older requiring dietary management of hyperglycemia. Contains 1.27 milligrams of iron per 100 Calories.

Caution: When used for tube feedings, follow physician's instructions. Additional fluid requirements should be met by giving water with or after feedings.

Jevity: A nutritionally complete, isotonic, high-nitrogen, liquid food with added soy polysaccharide fiber, selenium, chromium, molybdenum, taurine, and L-carnitine for oral and tube feeding. For adults and children age 4 and older requiring increased calories in a restricted volume. For persons intolerant to low residue feedings. Fiber level helps maintain normal bowel function. Contains 1.29 milligrams of iron per 100 Calories.

Caution: When used for tube feeding, follow physician's instructions. Additional fluid requirements should be met by serving water with or after feedings.

Osmolite: A nutritionally complete, isotonic, lactose-free, low-residue liquid food for oral or tube feeding. For adults and children age 4 and older requiring moderately electrolyte-restricted diets. Contains 0.90 milligram of iron per 100 Calories.

Caution: When used for tube feedings, follow the physician's instructions. Additional fluid requirements should be met by giving water with or after feedings.

Osmolite HN: A nutritionally complete, high-nitrogen, isotonic, lactose-free, low-residue liquid food for oral or tube feeding. For adults and children age 4 and older with increased protein needs. Also for persons intolerant to hyperosmolar feedings or with fat digestion and absorption problems. Contains 1.29 milligrams of iron per 100 Calories.

Caution: When used for tube feedings, follow physician's instructions. Additional fluid requirements should be met by giving water with or after feedings.

Pediasure: A nutritionally complete, virtually lactose-free, gluten-free liquid food for oral or tube feeding. Use as a supplement or for total enteral nutrition of children 1 to 6 years of age who are undernourished and/or have decreased food intake due to illness, diminished appetite, or inability to eat. Contains 1.4 milligrams of iron per 100 Calories.

Caution: THIS FORMULA IS NOT INTENDED FOR INFANTS UNDER 1 YEAR OLD UNLESS SPECIFIED BY A PHYSICIAN. When used for tube feedings, follow the physician's instructions. Additional fluid requirements should be met by giving water with or after feedings.

Pulmocare: A nutritionally complete, high-fat, low-carbohydrate, lactose-free liquid food for oral and tube feeding. For the dietary management of respiratory insufficiency in adults and children age 4 and older. Designed to reduce carbon dioxide production. Caloric distribution (16.7 percent protein, 28.1 percent carbohydrate, and 55.2 percent fat) is uniquely different from most infant formulas, exempt formulas, and adult medical foods as well as general diets. Long-term use has not been evaluated. Contains 1.28 milligrams of iron per 100 Calories.

Two Cal HN: A nutritionally complete, high-calorie, high-nitrogen, lactose-free liquid food for oral or tube feeding. For adults and children 4 years of age and older. Useful as a concentrated dietary source when voluntary food intake is inadequate to meet nutrient needs. Appropriate for severely hypermetabolic or fluid-restricted persons. Contains 0.95 milligram of iron per 100 Calories.

Caution: When used for tube feedings, follow the physician's instructions. Additional fluid requirements should be met by giving water with or after feedings.

Vital High Nitrogen: A nutritionally complete, high-nitrogen, partially hydrolyzed diet for oral or tube feeding. For adults and children age 4 and older with impaired gastrointestinal function. Contains 1.2 milligrams of iron per 100 calories.

Caution: When used for tube feedings, follow the physician's instructions. Additional fluid requirements should be met by giving water with or after feedings.

Sandoz Nutrition

Fiber Source: A nutritionally complete, lactose- and gluten-free, liquid formula with added soy fiber for oral or tube feeding. For adults and children age 4 and older with problems meeting protein needs. Also appropriate for persons on sodium- and volume-restricted diets. Contains 12 milligrams of iron per 100 calories.

Caution: When used for tube feedings, follow the physician's instructions. For children, modify nutrients administered to meet Recommended Dietary Allowances for the age group involved. Additional fluid requirements should be met by giving water with or after feedings.

Fiber Source HN: A nutritionally complete, high-nitrogen, lactose- and gluten-free liquid formula with added soy fiber for oral or tube feeding. For adults and children 4 years of age and older with elevated protein needs. Also appropriate for persons on sodium- and volume-restricted diets. Contains 1 milligram of iron per 100 Calories.

Caution: When used for tube feedings, follow the physician's instructions. Additional fluid requirements should be met by giving water with or after feedings.

Isosource: A nutritionally complete, lactose-, gluten-, and fiber-free formula for oral or tube feeding. For adults with problems meeting protein needs. Also appropriate for persons on sodium- and volume-restricted diets. Contains 1 milligram of iron per 100 Calories.

Caution: When used for tube feedings, follow the physician's instructions. For children, modify nutrients administered to meet Recommended Dietary Allowances for the age group involved. Additional fluid requirements should be met by giving water with or after feedings.

Isosource HN: A nutritionally complete, high-nitrogen, lactose-, gluten- and fiber-free formula for oral and tube feeding. For adults with elevated protein needs or on sodium-restricted diets. Also appropriate for volume-sensitive persons. Contains 1 milligram of iron per 100 Calories.

Caution: When used for tube feedings, follow the physician's instructions. For children, modify nutrients administered to meet Recommended Dietary Allowances for the age group involved. Additional fluid requirements should be met by giving water with or after feedings.

Isotein HN: A nutritionally complete, high-protein, and gluten-free, isotonic formula for oral and tube feeding. Contains no purines. For older children and adults requiring a concentrated source of nutrition. Contains 0.86 milligram of iron per 100 Calories.

Caution: **USE THIS PRODUCT ONLY UNDER MEDICAL SUPERVISION.** For children, modify nutrients administered to meet Recommended Dietary Allowances for the age group involved. Additional fluid requirements should be met by giving water with or after feedings.

Meritene Liquid: A nutritionally complete, high protein formula for oral or tube feeding. For adults and children age 4 and older with elevated protein and calorie needs. Also appropriate for persons on sodium- and gluten-restricted diets. Contains 1.5 milligrams of iron per 100 Calories.

Caution: When used for tube feedings, follow the physician's instructions. For children, modify nutrients administered to meet Recommended Dietary Allowances for the age group involved. Additional fluid requirements should be met by giving water with or after feedings.

Precision Isotonic Diet: A nutritionally complete, lactose- and gluten-free, low-residue isotonic formula for oral and tube feeding. For adults and children age 4 and older who have problems meeting protein needs. Also appropriate for diabetics and for persons on sodium-restricted diets. Contains 1.2 milligrams of iron per 100 Calories.

Caution: **USE THIS PRODUCT ONLY UNDER MEDICAL SUPERVISION.** When used for tube feedings, follow the physician's instructions. For children, modify nutrients administered to meet Recommended Dietary Allowances for the age group involved. Additional fluid requirements should be met by giving water with or after feedings.

Resource Instant Crystals: A nutritionally complete, lactose-free, low-residue formula for oral and tube feeding. For adults requiring nutritional supplementation. Also appropriate for persons with anorexia, malnutrition, and lactose intolerance. Contains 0.89 milligram of iron per 100 Calories.

Caution: When used for tube feedings, follow the physician's instructions. For children, modify nutrients administered to meet Recommended Dietary Allowances for the age group involved. Additional fluid requirements should be met by giving water with or after feedings.

Resource Liquid: A nutritionally complete, lactose- and gluten-free, low-sodium, low-residue formula for oral and tube feeding. For adults with problems meeting protein and calorie needs. Also appropriate for persons with anorexia, malnutrition, and impaired swallowing. Contains 0.90 milligram of iron per 100 Calories.

Caution: When used for tube feedings, follow the physician's instructions. For children, modify nutrients administered to meet Recommended Dietary Allowances for the age group involved. Additional fluid requirements should be met by giving water with or after feedings.

Resource Plus: A nutritionally complete, high-calorie, lactose- and gluten-free, low-residue, low-sodium formula for oral and tube feeding. For adults with problems meeting protein requirements, increased calorie and nutrient needs, on sodium-restricted diets, or when fluid intake is restricted. Also appropriate for persons with anorexia, malnutrition, and impaired swallowing. Contains 0.96 milligram of iron per 100 Calories.

Caution: When used for tube feedings, follow the physician's instructions. For children, modify nutrients administered to meet Recommended Dietary Allowances for the age group involved. Additional fluid requirements should be met by giving water with or after feedings.

Sherwood Medical Company

Comply: A nutritionally complete, high-calorie, lactose-free formula for oral or tube feeding. For adults and children age 4 and older who have increased calorie needs or restricted fluid intake. Contains 1.2 milligrams of iron per 100 Calories.

Caution: **USE THIS PRODUCT ONLY UNDER MEDICAL SUPERVISION.** Fluid balance should be closely monitored, especially when abnormal fluid losses are present or the person is unable to express thirst. Additional water may be needed to meet daily fluid requirements.

Magnacal: A nutritionally complete, high-calorie, low-residue, lactose-free, low-sodium formula for oral or tube feeding. For adults and children age 4 and older requiring a high caloric intake in a low volume. Contains 2.0 milligrams of iron per 100 Calories.

Caution: **USE THIS PRODUCT ONLY UNDER MEDICAL SUPERVISION.** Fluid balance should be closely monitored, especially when abnormal fluid losses are present or the person is unable to express thirst. Additional water may be needed to meet daily fluid requirements.

C-3. Medical Foods: Complete Elemental Diets

Elemental or chemically-defined diets are semisynthetic diets containing a full range of basic nutritional components. They contain no polypeptides or peptones and can be absorbed without the assistance of a fully operating digestive system. They contain no fiber and have a minimum residue (Russell, 1981b).

For the normal patient subjected to a short-term treatment, elemental diets appear to be effective as the sole source of nutrition or as a nutritional supplement to normal foods. However, the diets may or may not be adequate for persons with moderate or severe nutritional deficiency (Russell, 1981a). Although these diets are relatively unpalatable and often are administered by nasogastric tubes, they may be given orally.

There are a variety of elemental diets on the market place. The specific benefits must be carefully matched with the needs of the individual. All patients must be monitored throughout the period of therapy so that doses can be planned and scheduled correctly and nutrient deficiencies can be avoided (Russell, 1981a).

Elemental diets are designed for adults. However, occasionally when an infant cannot tolerate other specialized formulas, elemental diets may be cautiously and carefully used as a short-term alternative to total parenteral nutrition (Brady et al., 1986). These diets have been fed to infants with intractable diarrhea syndrome, short bowel syndrome, protein-sensitive enteropathies, and glycogen storage disease (Christie, 1981).

Attention should be given to the potential hazards associated with the use of these diets. Problems include gastrointestinal side effects, disturbance of water balance, insulin deficiency, aspiration, nutritional complications/deficiencies, effects on specific organs, and susceptibility to drugs. All symptoms may not occur but they are listed to inform the reader of the potential problems that may occur (Hare and Russell, 1981).

The limitations of elemental diets should be noted. They do not meet the total nutrient requirements for infants. Supplementation of certain vitamins and minerals may be necessary since the limited volume consumed by the infant results in inadequate intake of some nutrients (Brady et al., 1986).

A detailed description of elemental diets is listed below. **These products are not to be used for parenteral nutrition.** Where applicable, the caution statement is based on information taken from company literature. **Appendix C-3** provides a quick reference for additional information on these elemental diets.

Kendall McGaw Laboratories, Inc.

Traum-Aid HBC: A nutritionally complete, low-residue, high-branched-chain amino acids, high-nitrogen, elemental diet for oral or tube feeding. For the dietary management of hypercatabolic adults experiencing sepsis, protein/calorie malnutrition, or other nutritional deficiencies. Contains 0.6 milligram of iron per 100 Calories.

Caution: USE THIS PRODUCT ONLY UNDER MEDICAL SUPERVISION. PRODUCT SHOULD NOT BE FED TO PERSONS WITH INBORN ERRORS OF AMINO ACID METABOLISM. Persons on prolonged use of this product should be monitored. For osmotically-sensitive individuals, Traum-Aid HBC may be administered slowly or diluted to one-half or three-quarters strength to reduce osmolality. Use in children or pregnant and lactating women has not been studied.

Mead Johnson Nutritionals

Criticare HN: A nutritionally complete, high-nitrogen, lactose-free, minimum-residue, elemental diet for oral or tube feeding. For adults and children age 4 and older. Useful for inflammatory bowel disease, short-gut syndrome, nonspecific malabsorptive/maldigestive conditions, and cystic fibrosis. May be used by persons on sodium-restricted diets. For oral use, flavor may need to be enhanced. Contains 0.88 milligram of iron per 100 Calories.

Caution: For tube feedings, dilute Criticare HN to half strength initially, and gradually increase to full strength.

Norwich Eaton Pharmaceutical, Inc.

Tolerex: A nutritionally complete, lactose-free, low-fat, essentially no residue, elemental diet for oral or tube feeding. For dietary management in adults with impaired digestion and/or absorption, secondary to a variety of diseases and disorders associated with the gastrointestinal tract. Well tolerated by persons with known food sensitivities. Also useful in the dietary management of infants and neonates suffering from intractable diarrhea and as a transitional diet between parenteral and normal oral feeding. When used for oral feedings, neonates and other very young children will usually accept the diet lukewarm and unflavored; older children may prefer the diet chilled and flavored. Contains 0.6 milligram of iron per 100 Calories.

Caution: USE THIS PRODUCT UNDER MEDICAL SUPERVISION. Special precautions should be taken in administering Tolerex to infants and children. Certain nutrients may need to be supplemented. In particular, intake of calcium, phosphorus, vitamin D, vitamin C (neonates only), and iron may not meet the Recommended Dietary Allowances for pediatric age groups. During the first 2 days of use, product may need to be overdiluted for osmotically-sensitive persons, gradually titrating up to full strength. Fluid intake and excretion should be monitored throughout treatment, together with changes in body weight and biochemical parameters.

Vivonex T.E.N.: A nutritionally complete, high-nitrogen elemental diet for total enteral nutrition via oral or tube feeding. For dietary management of adults with stress,

impaired digestion and absorption, malnutrition and cachexia, and for food sensitivities. When used for oral feedings, neonates and other very young children will usually accept the diet lukewarm and unflavored; older children may prefer the diet chilled and flavored. Contains 0.9 milligram of iron per 100 Calories.

Caution: USE THIS PRODUCT ONLY UNDER MEDICAL SUPERVISION.

During first few days of use, product should be diluted and concentration gradually increased to full strength. Special precautions should be taken in administering Vivonex T.E.N. to infants and children. Certain nutrients may need to be supplemented. In particular, intake of calcium, phosphorus, vitamin D, vitamin C (neonates only), and iron may not meet the Recommended Dietary Allowances for pediatric age groups. Diabetics and persons with renal insufficiency receiving this product should be closely monitored. Fluid intake and excretion should be monitored throughout treatment together with changes in body weight and biochemical parameters.

Sherwood Medical Company

Accupez HPF: A nutritionally complete, high-nitrogen, low-residue, hydrolyzed protein elemental formula for oral and tube feeding. For adults and children age 4 and older with malabsorptive/maldigestive disorders. Contains 1.1 milligrams of iron per 100 Calories.

Caution: USE THIS PRODUCT ONLY UNDER MEDICAL SUPERVISION.

Fluid balance should be closely monitored, especially when abnormal fluid losses are present or the person is unable to express thirst. Additional water may be needed to meet daily fluid requirements.

**C-4. Medical Foods:
Incomplete Modular
Diets**

Modular formulas should be used under close professional supervision. They are incomplete formulas that allow stepwise introduction of specific nutrients into the diet in a logical sequence (Nichols, 1988). They are becoming increasingly useful for modifying the content of protein, carbohydrate, fat, vitamins, or minerals in feedings. With modular formulas, the total formula can be tailored to a given type of malabsorption syndrome. Many of these formulas may be added to existing formulas that are used for oral and tube feedings for infants, children, or adults.

Below is a detailed description for modular formulas. **These products should not be used for parenteral nutrition.** Where applicable, the caution statement is based on information taken from company literature. **Appendix C-4** provides a quick reference for additional information on these products. Metabolic modules are presented on pages 15-17 and pages 25-28. **Appendixes B-2 and C-1** provide quick references for additional information for these products as exempt infant formulas and medical foods, respectively.

Mead Johnson Nutritionals

(See Metabolic Modules on pages 15-17 and 25-28.)

Casec: A nutritionally incomplete, low-sodium, protein (calcium caseinate) supplement for oral or tube feeding. Useful as a source of extra protein to supplement sodium-restricted, low-cholesterol, or low-fat diets. May be mixed with foods or blended into milk drinks. Available to the retail pharmacy for special use when ordered by the physician. Contains no iron.

Caution: When Casec is used for tube feedings, follow the physician's instructions. Additional fluid requirements should be met by giving water with or after feedings. Product is designed for use as a food supplement only. It should not be used for weight reduction.

MCT Oil: A nutritionally incomplete fat (medium-chain triglycerides) supplement. For the nutritional management of persons who cannot efficiently digest and absorb conventional long-chain triglycerides. MCT oil should be mixed with fruit juices, salads, sauces, etc. Recipes available upon request from manufacturer. Contains no iron.

Portagen and Pregestimil are nutritionally complete exempt infant formulas containing MCT oil as the primary source of fat.

Caution: MCT oil should be taken in divided doses.

Moducal: A nutritionally incomplete, readily digestible, carbohydrate (maltodextrin) supplement for oral or tube feeding. For persons who have difficulty digesting other carbohydrate forms. May be used to provide additional calories when needed or when caloric intake is limited. May be added to water, other beverages, or food. Contains no iron.

Caution: **DO NOT USE MODUCAL FOR GENERAL FEEDING. USE ONLY UNDER THE SUPERVISION OF THE ATTENDING PHYSICIAN.** Infants receiving this formula need to be monitored closely and the instructions for use and preparation should be followed carefully.

Ross Laboratories

Polycose: A nutritionally incomplete carbohydrate (glucose polymers) source for oral or tube feeding. For persons with increased caloric needs or unable to meet their caloric needs through the normal diet. Particularly useful in supplying carbohydrate calories for protein-, electrolyte-, and fat-restricted diets. May be used for extended periods with diets containing all other essential nutrients. May be added to foods or liquids. Contains no iron.

Caution: WHEN POLYCOSE IS USED FOR INFANTS, DO NOT FEED UNDI-LUTED. USE ONLY AS SPECIFICALLY DIRECTED BY A PHYSICIAN.

Polydose is not a balanced diet and should not be used as a sole source of nutrition.

ProMod: A nutritionally incomplete, low-lactose, protein (whey) source for oral or tube feeding. Provides extra protein to individuals who have increased protein needs and are unable to meet their protein needs with a normal diet. Useful in controlling protein intake in protein-restricted diets. May be added to nutritional supplements or table foods. Contains no iron.

Caution: WHEN PROMOD IS USED FOR INFANTS, DO NOT FEED UNDI-LUTED. USE ONLY AS SPECIFICALLY DIRECTED BY A PHYSICIAN OR OTHER HEALTH PROFESSIONAL. ProMod is not a balanced diet and should not be used as a sole source of nutrition.

Sherwood Medical Company

Propac: A nutritionally incomplete protein (whey) source. Provides extra protein to persons who have increased protein needs and are unable to meet their protein needs with a normal diet. May be added to oral supplements, tube feedings, or table foods. Contains no iron.

Caution: USE PROPAC ONLY UNDER MEDICAL SUPERVISION. Propac should be used for persons with adequate renal function. It may be used for dialysis patients under a physician's supervision. Product is designed for use as a supplement only. It should not be used for weight reduction.

Sumacal: A nutritionally incomplete carbohydrate (maltodextrin) source for oral or tube feeding. Useful as a source of calories for persons with increased needs or unable to meet calorie needs through a normal diet. May be added to nutritional supplements, other beverages, and table foods. Contains no iron.

Caution: USE SUMACAL ONLY UNDER MEDICAL SUPERVISION. Glucose tolerance should be monitored in patients using Sumacal. An excessive carbohydrate load may produce glycosuria.

Microlipid: A nutritionally incomplete fat (safflower oil emulsion) source. Useful for persons needing an extra source of calories from fat. Product is a source of linoleic acid. May be added to oral supplements, tube feedings, other beverages, and table foods. Contains no iron.

Caution: USE MICROLIPID ONLY UNDER MEDICAL SUPERVISION. Other essential nutrients should be supplied from additional sources.

Wyeth-Ayerst Laboratories

“EDW” (Electrodialyzed Whey): A nutritionally incomplete protein (whey) supplement. Contains lactose and limited amounts of vitamins and minerals. Useful for persons requiring a concentrated form of high biological value protein, such as with renal insufficiency. Recipes available upon request from the manufacturer.

Caution: “EDW” should be used to supplement the diet under the direction of the physician or other health care professional.

III. Company Resources

Carnation Company
Nutritional Products Division
5045 Wilshire Boulevard
Los Angeles, California 90036
Consumer Telephone Numbers: 1-800-782-7766 (Good Start)
1-800-242-5200 (Good Nature Follow-up Formula)

Carnation Infant Nutrition Products Fact Book. Carnation Company, 1989.

Gerber Products Company
Fremont, Michigan 49412
Consumer Telephone Numbers: 1-800-828-9119 (Gerber Baby Formulas)
1-800-443-7237 (All other products)

Company literature, 1989.

Kendall McGaw Laboratories, Inc.
2525 McGaw Avenue
Irvine, California 92714-5895
Consumer Telephone Number: 1-800-854-6851
In California and Alaska call collect: 1-714-660-2147.

Company literature, 1988.

Loma Linda Foods
11503 Pierce Street
Riverside, California 92515
Consumer Telephone Number: 1-800-932-5525

Company product documentation sheets, 1989.

Mead Johnson Nutritionals
2400 W. Lloyd Expressway
Evansville, Indiana 47721
Consumer Telephone Numbers: 1-800-222-9123 (ProSobee, Nutramigen, Pregestimil)
1-812-429-6437 (All other products)

Pediatric Products Handbook. Mead Johnson Nutritionals, 1989.

Enteral Nutritional Product Handbook. Mead Johnson Nutritionals, 1988.

Dietary Management of Metabolic Disorders. Mead Johnson Nutritionals, 1989.

Mead Johnson Special Metabolic Modules. Mead Johnson Nutritionals, 1988.

Norwich Eaton Pharmaceuticals, Inc.
P.O. Box 191
Norwich, New York 13815-0191
Consumer Telephone Number: 1-607-335-2565

Company literature, 1983.

Personal communication with Norwich Eaton Pharmaceuticals, Inc., 1987.

Ross Laboratories
625 Cleveland Avenue
Columbus, Ohio 43216
Consumer Telephone Number: 1-614-229-7900

Product Handbook. Ross Laboratories, 1988.

Using Concentrated Formulas and Caloric Supplements to Meet Special Infant Feeding Needs. Ross Laboratories, 1987.

Meeting the Special Nutrients Needs of Low-Birthweight Infants. Ross Laboratories, 1985.

The Use of Hydrolysate Feedings in Infancy: Alimentum Protein Hydrolysate Formula With Iron. Ross Laboratories, 1988.

"Composition of Medical Foods for Infants, Children and Adults with Metabolic Disorders," Ross Laboratories, November 1989.

"Composition of Feedings for Infants and Young Children in the Hospital," Ross Laboratories, November 1989.

Sandoz Nutrition
5320 West 23rd Street
Minneapolis, Minnesota 55416
Consumer Telephone Number: 1-800-999-9978

Company literature, 1990.

Sherwood Medical
1831 Olive Street
St. Louis, Missouri 63103
Consumer Telephone Number: 1-800-428-4400

Company literature, 1987, 1988, 1989.

Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, Pennsylvania 19101
Consumer Telephone Number: 1-800-950-5099

Wyeth Hospital Infant Feeding System: a special service for newborn nurseries and pediatric wards, Wyeth Laboratories, 1986.

Company laboratory data, Wyeth-Ayerst Laboratories, 1989.



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Nichols, B.L.: "Infant Feeding Practice." In Tsang, R.C. and Nichols, B.L., eds.: *Nutrition During Infancy*. Philadelphia: Hanley and Belfus, Inc., pp. 367-377, 1988.

Rassin, D.K., Sturman, J.A., and Guall, G.E.: "Taurine and other free amino acids in milk of man and other mammals." Early Human Development 2:1, 1978.

Russell, R.I.: "Formulations of elemental diets." In: R.I. Russell, ed.: *Elemental Diets*. Boca Raton: CRC Press, Inc., pp. 65-76, 1981a.

Russell, R.I.: "Historical background and development of elemental diets." In R.I. Russell, ed.: *Elemental Diets*. Boca Raton: CRC Press, Inc., 1981b.

Schanler, R.J.: "Special methods in feeding the preterm infant." In Tsang, R.C. and Nichols, B.L., eds.: *Preterm Infants*. New York: Marcel Dekker, pp. 314-325, 1985.

Sarett, H.P.: "The modern infant formula." In Bond, J.T., et al, eds.: *Infant and Child Feeding*. New York: Academic Press, pp. 99-121, 1981.

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V. Appendixes

Appendix A-1: Infant Formulas: Milk Based

Product	Caloric Density a Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/Qt	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
** Carnation Company								
Carnation Good Start w/Iron	20 Cal/fl. oz.	whey hydrolysate	lactose, maltodextrin	palm olein, high oleic safflower oil, coconut oil	265	9.6	pro - 9.8% cho - 44.2% fat - 46.0%	pwd.: 12 oz., yields 87.2 fl. oz.
Carnation Follow-up Formula w/Iron	20 Cal/fl. oz.	nonfat milk	glucose, high maltose corn syrup, lactose	palm oil, high oleic safflower oil, corn oil	345	12	pro - 12% cho - 53% fat - 35%	rtf.: 32 fl. oz., pwd.: 12 oz., yields 80.8 fl. oz.
** Gerber Products Company								
Gerber Baby Formula w/Iron, Gerber Baby Formula	20 Cal/fl. oz.	nonfat milk	lactose	soy or corn and coconut oils	320	11.5 +++	pro - 9% cho - 43% fat - 48%	liq. conc.: 13 fl. oz. rtf.: 32 fl. oz. pwd.: 1 lb., yields 118 fl. oz.
** Mead Johnson Nutritionals								
Enfamil w/Iron, Enfamil	20 Cal/fl. oz.	reduced minerals whey, nonfat milk	lactose	coconut and soy or corn oils	300	12 +++	pro - 9% cho - 41% fat - 50%	liq. conc.: 13 fl. oz. rtf.: 32, 8, 6, 4 fl. oz. pwd.: 1 lb., yields 120 fl. oz.

1/ At normal dilution.

2/ (+++) Gerber Baby Formula and Enfamil each contain 1.0 milligram of iron per quart of formula.

Product	Caloric Density @ Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/Qt	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
** Ross Laboratories								
Similac w/Iron, Similac	20 Cal/fl. oz.	nonfat milk	lactose	coconut and soy or corn oils	300	11.5 +++	pro - 8.9% cho - 42.8% fat - 48.3%	liq. conc.: 13 fl. oz. rtf.: 32, 8, 4 fl. oz. pwd.: 1 lb., yields 116 fl. oz.
** Wyeth-Ayerst Laboratories								
SMA, SMA lo-iron	20 Cal/fl. oz.	nonfat milk, reduced minerals whey	lactose	oleo, coconut, oleic and soy oils	300	11.4 +++	pro - 8.9% cho - 42.9% fat - 48.2%	liq. conc.: 13 fl. oz. rtf.: 32, 8, 4 fl. oz. pwd.: 1 lb., yields 120 fl. oz.

1/ At normal dilution.

2/ (+++) Similac and SMA lo-iron each contain 1.4 milligrams of iron per quart of formula.

Appendix A-2: Infant Formulas: Soy Based

Product	Caloric Density @ Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/Qt	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
1/								
** Loma Linda Foods								
Soyalac	20 Cal/fl. oz.	soybean solids, corn syrup, L-methionine	sucrose, soybean carbohydrate	soy oil	240	12.2	pro - 12.2% cho - 39.2% fat - 48.6%	liq. conc.: 13 fl. oz. rtf.: 32 fl. oz. pwd.: 14 oz., yields 102 fl. oz.
I-Soyalac	20 Cal/fl. oz.	soy protein isolate, L-methionine	sucrose, tapioca dextrin	soy oil	270	12.2	pro - 12.2% cho - 39.2% fat - 48.6%	liq. conc.: 13 fl. oz. rtf.: 32 fl. oz.
** Mead Johnson Nutritionals								
ProSobee	20 Cal/fl. oz.	soy protein isolate L-methionine	corn syrup solids	coconut and corn or soy oils	200	12	pro - 12% cho - 40% fat - 48%	liq. conc.: 13 fl. oz. rtf.: 32, 8 fl. oz. pwd.: 14 oz, yields 102 fl. oz.
** Ross Laboratories								
Isomil	20 Cal/fl. oz.	soy protein isolate	corn syrup, sucrose	coconut and soy or corn oils	240	11.5	pro - 10.6% cho - 40.4% fat - 49.1%	liq. conc.: 13 fl. oz. rtf.: 32, 8 fl. oz. pwd.: 14 oz., yields 102 fl. oz.
Isomil SF	20 Cal/fl. oz.	soy protein isolate	Polyucose glucose polymers	soy and coconut oils, mono- and di-glycerides	150	11.5	pro - 10.6% cho - 40.4% fat - 49.1%	liq. conc.: 13 fl. oz. rtf.: 32 fl. oz.

1/ At normal dilution.

Product	Caloric Density a Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/Ot	Caloric Distribution	Packaging
Nursoy	20 Cal/fl. oz.	soy protein isolate	sucrose or corn syrup solids	oleo, coconut, oleic and soy oils	296	10.9	pro - 12.3% cho - 40.3% fat - 47.4%	liq. conc.: 13 fl. oz. rtf.: 32 fl. oz. pwd.: 1lb., yields 107 fl. oz.

**** Wyeth-Ayerst Laboratories**

Nursoy

1/ At normal dilution.

Appendix A-3: Infant Formulas: Combination Milk- and Soy-Based

Product	Caloric Density @ Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/qt	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
1/								
** Ross Laboratories								
Advance	16 Cal/fl. oz.	nonfat milk, soy protein isolate	corn syrup, lactose	soy and corn oils	200	9.5	pro - 15% cho - 40% fat - 45%	liq. conc.: 13 fl. oz. rtf.: 32 fl. oz.
1/ At normal dilution.								

Appendix B-1: Exempt Infant Formulas: For Preterm and Low-Birthweight Infants

Product	Caloric Density @ Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H ₂ O	Iron Mg/qt	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
** Mead Johnson Nutritionals								
Enfamil Premature Formula w/iron, Enfamil Premature Formula	20 Cal/fl. oz.	whey protein concentrate, nonfat milk	corn syrup solids, lactose	soy oil, MCT, coconut oil	240	12 +++	pro - 12% cho - 44% fat - 44%	rtf.: 4 fl. oz.
Enfamil Premature Formula w/iron, Enfamil Premature Formula	24 Cal/fl. oz.	whey protein concentrate, nonfat milk	corn syrup solids, lactose	soy oil, MCT, coconut oil	300	14.4 +++	pro - 12% cho - 44% fat - 44%	rtf.: 4 fl. oz.
Enfamil Human Milk Fortifier 3/	N/A	whey protein concentrate, casein	corn syrup solids, lactose	negligible	+120 ++	0	pro - 20% cho - 77% fat - 3%	pwd.: case of 100 packets, 0.034 oz. each.
** Ross Laboratories								
Similac Special Care 20	20 Cal/fl. oz.	nonfat milk, whey protein concentrate	hydrolyzed cornstarch, lactose	MCT, soy and coconut oils	250	2.4	pro - 11% cho - 42% fat - 47%	rtf.: 4 fl. oz.
Similac Special Care 24 w/iron, Similac Special Care 24	24 Cal/fl. oz.	nonfat milk, whey protein concentrate	hydrolyzed cornstarch, lactose	MCT, soy and coconut oils	300	14.2 +++	pro - 11% cho - 42% fat - 47%	rtf.: 4 fl. oz.

1/ At normal dilution.
 2/ (+++) Enfamil Premature Formula (20 Cal/fl. oz.) contains 1.6 milligrams of iron; Enfamil Premature Formula (24 Cal/fl. oz.) contains 1.92 milligrams of iron; and Similac Special Care 24 contains 2.8 milligrams of iron per quart of formula.
 3/ (++) When added to breastmilk, the osmolality increases to 420.

Appendix B-1: Exempt Infant Formulas: For Preterm and Low-Birthweight Infants (Contd.)

Product	Caloric Density a Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/Qt	Caloric Distribution	Packaging
1/								
** Ross Laboratories								
Similac Natural Care	24 Cal/fl. oz.	nonfat milk, whey protein concentrate	hydrolyzed cornstarch, lactose	MCT, soy and coconut oils	300	2.8	pro - 11% cho - 42% fat - 47%	rtf.: 4 fl. oz.
Similac PM 60/40	20 Cal/fl. oz.	whey protein concentrate, sodium caseinate	lactose	corn and coconut oils	280	1.4	pro - 9% cho - 41% fat - 50%	rtf.: 4 fl. oz. pwd.: 1 lb., yields 120 fl oz.
** Wyeth-Ayerst Laboratories								
"Preemie" SMA 20	20 Cal/fl. oz.	nonfat milk, whey protein concentrate	maltodextrins, lactose,	coconut, oleic, oleo, and soy oils, MCT	268	2.8	pro - 11.9% cho - 41.5% fat - 46.7%	rtf.: 4 fl. oz.
"Preemie" SMA 24	24 Cal/fl. oz.	nonfat milk, whey protein concentrate	maltodextrins, lactose	coconut, oleic, oleo, and soy oils, MCT	280	2.8	pro - 9.6% cho - 41.9% fat - 48.5%	rtf.: 4 fl. oz.
1/ At normal dilution.								

Appendix B-2: Exempt Infant Formulas: For Metabolic Disorders

Product	Caloric Density @ Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H ₂ O	Iron Mg/qt	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
** Mead Johnson Nutritionals								
Lofenalac	20 Cal/fl. oz.	casein hydro- lysate, amino acids	corn syrup solids, modified tapioca starch	corn oil	360	12	pro - 13% cho - 52% fat - 35%	pwd.: 1 lb., yields 106 fl. oz.
Low Phe/Tyr Diet Powder (Product 3200AB)	20 Cal/fl. oz.	casein hydro- lysate, amino acids	corn syrup solids, modified tapioca starch	corn oil	360	12	pro - 13% cho - 52% fat - 35%	pwd.: 1 lb., yields 102 fl. oz.
MSUD Diet Powder	20 Cal/fl. oz.	amino acids	corn syrup solids, modified tapioca starch	corn oil	360	12	pro - 7% cho - 54% fat - 39%	pwd.: 1 lb., yields 108 fl. oz.
Low Methionine Diet Powder (Product 3200k)	20 Cal/fl. oz.	soy protein isolate	corn syrup solids	coconut and corn oils	168	12	pro - 12% cho - 40% fat - 48%	pwd.: 14 oz., yields 102 fl. oz.
Mono- and Disaccharide- Free Diet Powder (Product 3232A)	20 Cal/fl. oz.	casein hydro- lysate, amino acids	modified tapioca starch	MCT and corn oil	250	12	pro - 11.2% cho - 53.6% fat - 37.8%	pwd.: 1 lb., yields 179 fl. oz.
Protein Free Diet Powder (Product 80056)	17 Cal/fl. oz.	0	corn syrup solids, modified tapioca starch	corn oil	200	12	pro - 0 cho - 59% fat - 41%	pwd.: 1 lb, yields 128 fl. oz.

1/ At normal dilution.

Appendix B-2: Exempt Infant Formulas: For Metabolic Disorders (Contd.)

Product	Caloric Density Per 100 Grams	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
					1/	2/		3/
** Mead Johnson Nutritionals, Distributor								
Module PKU 1	280	amino acids	sucrose	0	++	34	pro - 72% cho - 28% fat - 0	pwd.: 500 grams.
Module HIST 1	270	amino acids	sucrose	0	++	34	pro - 75% cho - 25% fat - 0	pwd.: 500 grams.
Module HOM 1	280	amino acids	sucrose	0	++	34	pro - 74% cho - 26% fat - 0	pwd.: 500 grams.
Module LYS 1	280	amino acids	sucrose	0	++	34	pro - 68% cho - 32% fat - 0	pwd.: 500 grams.
Module MSUD 1	280	amino acids	sucrose	0	++	34	pro - 59% cho - 41% fat - 0	pwd.: 500 grams.
Module OS 1	290	amino acids	sucrose	0	++	34	pro - 60% cho - 40% fat - 0	pwd.: 500 grams.
Module TYR 1	280	amino acids	sucrose	0	++	34	pro - 70% cho - 30% fat - 0	pwd.: 500 grams.

1/ (++) Osmolality depends on the prescription.

2/ Per 100 grams of product.

3/ Yield depends on the prescription.

Appendix B-2: Exempt Infant Formulas: For Metabolic Disorders (Contd.)

Product	Caloric Density Per 100 Grams	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H ₂ O	Iron Mg	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
** Mead Johnson Nutritionals, Distributor								
Module UCD 1	260	amino acids	sucrose	0	++	40	pro - 88% cho - 12% fat - 0	pwd.: 500 grams.
** Ross Laboratories, Distributor								
Analog XP	475	amino acids	corn syrup solids	peanut oil, refined animal fat, coconut oil	++	7	pro - 11% cho - 50% fat - 39%	pwd.: case of 10 containers, 3.5 oz. each.
Analog MSUD	475	amino acids	corn syrup solids	peanut oil, refined animal fat, coconut oil	++	7	pro - 11% cho - 50% fat - 39%	pwd.: case of 10 containers, 3.5 oz. each.
Analog XLYS, TRY	475	amino acids	corn syrup solids	peanut oil, refined animal fat, coconut oil	++	7	Pro - 11% cho - 50% fat - 39%	pwd.: case of 10 containers, 3.5 oz. each.
Analog XMET	475	amino acids	corn syrup solids	peanut oil, refined animal fat, coconut oil	++	7	pro - 11% cho - 50% fat - 39%	pwd.: case of 10 containers, 3.5 oz. each.
Analog XPHEN, TYR	475	amino acids	corn syrup solids	peanut oil, refined animal fat, coconut oil	++	7	pro - 11% cho - 50% fat - 39%	pwd.: case of 10 containers, 3.5 oz. each.

1/ (++) Osmolality depends on the prescription.

2/ Per 100 grams of product.

3/ Yield depends on the prescription.

Appendix B-2: Exempt Infant Formulas: For Metabolic Disorders (Contd.)

Product	Caloric Density Per 100 Grams	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
** Ross Laboratories, Distributor								
Analog XPHEN, TYR, MET	475	amino acids	corn syrup solids	peanut oil, refined animal fat, coconut oil	++	7	pro - 11% cho - 50% fat - 39%	pwd.: case of 10 containers, 3.5 oz each.
Analog XMET, THRE, VAL, ISOLEU	475	amino acids	corn syrup solids	peanut oil, refined animal fat, coconut oil	++	7	pro - 11% cho - 50% fat - 39%	pwd.: case of 10 containers, 3.5 oz. each.

1/ (++) Osmolality depends on the prescription.

2/ Per 100 grams of product.

3/ Yield depends on the prescription.

Appendix B-3: Exempt Infant Formulas: For Unusual Medical or Dietary Problems

Product	Caloric Density @ Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/Qt	Caloric Distribution	Packaging
=====								
** Mead Johnson Nutritionals								
Nutramigen	20 Cal/fl. oz.	casein hydrolysate, amino acids	corn syrup solids, modified cornstarch	corn oil	320	12	pro - 11% cho - 54% fat - 35%	liq. conc.: 13 fl. oz. rtf.: 32, 8 fl. oz., pwd.: 1 lb., yields 102 fl. oz.
Pregestimil	20 Cal/fl. oz.	casein hydrolysate, amino acids	corn syrup solids, modified cornstarch, dextrose	corn oil, MCT, high oleic safflower oil	320	12	pro - 11% cho - 41% fat - 48%	pwd.: 1 lb., yields 112 fl. oz.
Portagen	20 Cal/fl. oz.	sodium caseinate	corn syrup solids, sucrose	MCT, corn oil	230	12	pro - 14% cho - 46% fat - 40%	pwd.: 1 lb., yields 106 fl. oz.
** Ross Laboratories								
Alimentum Protein Hydrolysate	20 Cal/fl. oz.	amino acids, peptides	sucrose, tapioca starch	MCT, safflower and soy oils	370	11.4	pro - 11% cho - 41% fat - 48%	rtf.: 32, 8 fl. oz.
Calcilo XD	20 Cal/fl. oz.	whey protein concentrate, sodium caseinate	lactose	corn and coconut oils	280	1.4	pro - 9% cho - 41% fat - 50%	pwd.: 14.1 oz. yields 103 fl. oz.

1/ At normal dilution.

Appendix B-3: Exempt Infant Formulas: For Unusual Medical or Dietary Problems (Contd.)

Product	Caloric Density @ Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/Qt	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
1/								
** Ross Laboratories								
ProViMin 2/	#	caseinate	0	0	#	#	#	pwd.: case of 6 cans, 5.3 oz. each, yields 25 leveled tablespoons per can.
RCF	20 Cal/fl. oz.	soy protein isolate	0	soy and coconut oils	74	1.4	pro - 19.8% cho - 0 fat - 80.2%	liq. conc.: 13 fl. oz.
** Wyeth-Ayerst Laboratories								
S-14	20 Cal/fl. oz.	nonfat milk	lactose	oleo, coconut, oleic, and soybean oils	280	11.8	pro - 6.6% cho - 43.0% fat - 50.4%	pwd.: 1lb., yields 122 fl.oz.
S-29	20 Cal/fl. oz.	reduced minerals whey, whey protein concentrate	lactose	oleo, coconut, oleic, and soybean oils	360	11.8	pro - 10.3% cho - 59.6% fat - 30.1%	pwd.: 1 lb., yields 108 fl. oz.
S-44	20 Cal/fl. oz.	reduced minerals whey, whey protein concentrate	lactose	oleo, coconut, oleic, and soy oils	360	11.8	pro - 10.3% cho - 59.6% fat - 30.1%	pwd.: 1 lb., yields 108 fl. oz.

1/ At normal dilution.

2/ (#) Dependent upon quantities of product used and amount of carbohydrate and fat to be added.

Appendix C-1: Medical Foods: Diets for Metabolic Disorders

Product	Caloric Density a Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/Ot	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
					1/	2/		3/
** Kendall McGaw Laboratories, Inc.								
Amin-Aid	59.17 Cal/fl. oz.	essential amino acids, histidine	maltodextrin, sugar	soybean oil	700	0	pro - 4.0% cho - 74.8% fat - 21.1%	pwd.: case of 24 packets, 147.1 - 147.6 grams each.
Hepatic-Aid II	35.5 Cal/fl. oz.	essential and nonessential amino acids	maltodextrin, sugar	soybean oil	560	0	pro - 15.0% cho - 57.3% fat - 27.7%	pwd.: case of 24 packets, 86.1 - 88.7 grams each.
** Mead Johnson Nutritionals								
Phenyl-Free	25 Cal/fl. oz.	amino acids	sucrose, corn syrup solids, modified tapioca starch	corn and coconut oils	790	24	pro - 20% cho - 65% fat - 15%	pwd.: 1 lb., yields 74 fl. oz.

1/ (++) Osmolality depends on the prescription.

2/ Per 100 grams of product.

3/ Yield depends on the prescription.

Appendix C-1: Medical Foods: Diets for Metabolic Disorders (Contd.)

Product	Caloric Density Per 100 Grams	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
** Mead Johnson Nutritionals, Distributor								
Module PKU 2	300	amino acids	sucrose	0	++	15	pro - 91% cho - 9% fat - 0	pwd.: 500 grams.
Module PKU 3	280	amino acids	sucrose	0	++	21	pro - 96% cho - 4% fat - 0	pwd.: 500 grams.
Module HIST 2	300	amino acids	sucrose	0	++	15	pro - 91% cho - 9% fat - 0	pwd.: 500 grams.
Module HOM 2	290	amino acids	sucrose	0	++	15	pro - 93% cho - 7% fat - 0	pwd.: 500 grams.
Module LYS 2	300	amino acids	sucrose	0	++	15	pro - 84% cho - 16% fat - 0	pwd.: 500 grams.
Module MSUD 2	300	amino acids	sucrose	0	++	15	pro - 71% cho - 29% fat - 0	pwd.: 500 grams.
Module OS 2	300	amino acids	sucrose	0	++	15	pro - 74% cho - 26% fat - 0	pwd.: 500 grams.

1/ (++) Osmolality depends on the prescription.

2/ Per 100 grams of product.

3/ Yield depends on the prescription.

Appendix C-1: Medical Foods: Diets for Metabolic Disorders (Contd.)

Product	Caloric Density Per 100 Grams	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H ₂ O	Iron Mg	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
1/								
2/								
3/								
*** Mead Johnson Nutritional, Distributor								
Module TYR 2	300	amino acids	sucrose	0	++	15	pro - 84% cho - 16% fat - 0	pwd.: 500 grams.
Module UCD 2	290	amino acids	sucrose	0	++	15	pro - 92% cho - 8% fat - 0	pwd.: 500 grams.
*** Ross Laboratories, Distributor								
Maxamaid XP	350	amino acids	sucrose, hydrolyzed cornstarch	negligible	++	12	pro - 29% cho - 71% fat - 0	pwd.: case of 10 containers, 7 oz. each.
Maxamum XP	340	amino acids	sucrose, hydrolyzed cornstarch	negligible	++	23.5	pro - 46% cho - 54% fat - 0	pwd.: case of 10 containers, 7 oz. each.
Maxamaid MSUD	350	amino acids	sucrose, hydrolyzed cornstarch	negligible	++	12	pro - 29% cho - 71% fat - 0	pwd.: case of 10 containers, 7 oz. each.
Maxamum MSUD	340	amino acids	sucrose, hydrolyzed cornstarch	negligible	++	23.5	pro - 46% cho - 54% fat - 0	pwd.: case of 10 containers, 7 oz. each.

1/ (++) Osmolality depends on the prescription.

2/ Per 100 grams of product.

3/ Yield depends on the prescription.

Appendix C-1: Medical Foods: Diets for Metabolic Disorders (Contd.)

Product	Caloric Density Per 100 Grams	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
** Ross Laboratories, Distributor								
Maxamaid XMET	350	amino acids	sucrose, hydrolyzed cornstarch	negligible	++	12	pro - 29% cho - 71% fat - 0	pwd.: case of 10 containers, 7 oz. each.
Maxamaid XPHEN, TYR	350	amino acids	sucrose, hydrolyzed cornstarch	negligible	++	12	pro - 29% cho - 71% fat - 0	pwd.: case of 10 containers, 7 oz. each.
Maxamaid XMET, THRE, VAL, ISOLEU	350	amino acids	sucrose, hydrolyzed cornstarch	negligible	++	12	pro - 29% cho - 71% fat - 0	pwd.: case of 10 containers, 7 oz. each.
Maxamaid XLYS, TRY	350	amino acids	sucrose, hydrolyzed cornstarch	negligible	++	12	pro - 29% cho - 71% fat - 0	pwd.: case of 10 containers, 7 oz. each.

- 1/ (++) Osmolality depends on the prescription.
2/ Per 100 grams of product.
3/ Yield depends on the prescription.

Appendix C-2: Medical Foods: Complete Special Diets

Product	Caloric Density a Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H ₂ O	Iron Mg/Ot	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
1/								
** Mead Johnson Nutritionals								
Sustacal Liquid	30 Cal/fl. oz.	sodium and calcium caseinate, soy protein isolate	sucrose, corn syrup	soy oil	650 - 690	16	pro - 24% cho - 55% fat - 21%	rtf.: 32, 12, 8 fl. oz.
Sustacal with Fiber	31.3 Cal/fl. oz.	calcium and sodium caseinates, soy protein isolate	maltodextrin, sugar	corn oil	480	12	pro - 17% cho - 53% fat - 30%	rtf.: 8 fl. oz.
Sustacal HC	45 Cal/fl. oz.	calcium and sodium caseinates	corn syrup solids, sugar	corn oil	650	14.4	pro - 16% cho - 50% fat - 34%	rtf.: 8 fl. oz.
Sustagen	55 Cal/fl. oz.	nonfat milk, powdered whole milk, calcium caseinate	corn syrup solids, lactose, dextrose	milk fat	1100	18	pro - 24% cho - 68% fat - 8%	pwd.: 1 lb., yields 32 fl. oz.
Isocal	31.3 Cal/fl. oz.	sodium and calcium caseinates, soy protein isolate	maltodextrin	soy oil, MCT	270	9	pro - 13% cho - 50% fat - 37%	rtf.: 32, 12, 8 fl. oz.
Isocal HCN	59 Cal/fl. oz.	sodium and calcium caseinates	corn syrup	soy oil, MCT	640	17.2	pro - 15% cho - 40% fat - 45%	rtf.: 8 fl. oz.

1/ At normal dilution.

Appendix C-2: Medical Foods: Complete Special Diets (Contd.)

Product	Caloric Density @ Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/Qt	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
1/								
** Mead Johnson Nutritionals								
Isocal HN	31.3 Cal/fl. oz.	sodium and calcium caseinates, soy protein isolate	maltodextrin	soy oil, MCT	270	14.4	pro - 17% cho - 46% fat - 37%	rtf.: 8 fl. oz.
Lonalac	30 Cal/fl. oz.	casein	lactose	coconut oil	360	0	pro - 21% cho - 30% fat - 49%	pwd.: 1 lb., yields 77.2 fl. oz.
TraumaCal	44 Cal/fl. oz.	sodium and calcium caseinates	corn syrup, sugar	soy oil, MCT	490	8.4	pro - 22% cho - 38% fat - 40%	rtf.: 8 fl. oz.
** Ross Laboratories								
Enrich	32.5 Cal/fl. oz.	sodium and calcium cas - nates, soy protein isolate	hydrolyzed cornstarch, sucrose, soy polysaccharide	corn oil	480	12.24	pro - 14.5% cho - 55.0% fat - 30.5%	rtf.: 32, 8 fl. oz.
Ensure	31.3 Cal/fl. oz.	sodium and calcium caseinates, soy protein isolate	corn syrup, sucrose	corn oil	470	9	pro - 14% cho - 54.4% fat - 31.5%	rtf.: 32, 8 fl. oz.
Ensure Plus	44.4 Cal/fl. oz.	sodium and calcium caseinates, soy protein isolate	corn syrup, sucrose	corn oil	690	12	pro - 14.7% cho - 53.3% fat - 32.0%	rtf.: 32, 8 fl. oz., 1 liter ready-to-hang.

1/ At normal dilution.

Appendix C-2: Medical Foods: Complete Special Diets (Contd.)

Product	Caloric Density @ Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/at	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
1/								
** Ross Laboratories								
Ensure HN	31.3 Cal/fl. oz.	sodium and calcium caseinates, soy protein isolate	corn syrup, sucrose	corn oil	470	12.88	pro - 16.7% cho - 53.2% fat - 30.1%	rtf.: 32, 8 fl. oz.
Ensure Plus HN	44.4 Cal/fl. oz.	sodium and calcium caseinates, soy protein isolate	corn syrup, sucrose	corn oil	650	18	pro - 16.7% cho - 53.3% fat - 30.0%	rtf.: 8 fl. oz.
Glucerna	29.6 Cal/fl. oz.	sodium and calcium caseinates	hydrolyzed cornstarch, fructose	safflower and soy oils	375	11.73	pro - 16.7% cho - 33.3% fat - 50.0%	rtf.: 8 fl. oz.
Jevity	31.3 Cal/fl. oz.	sodium and calcium caseinates	hydrolyzed cornstarch, soy poly- saccharide	MCT, corn and soy oils	310	12.88	pro - 16.7% cho - 53.3% fat - 30.0%	rtf.: 32, 8 fl. oz., 1 liter ready-to-hang.
Osmolite	31.3 Cal/fl. oz.	sodium and calcium caseinates, soy protein isolate	hydrolyzed cornstarch	MCT, corn and soy oils	300	9	pro - 14.0% cho - 54.6% fat - 31.4%	rtf.: 32, 8 fl. oz., 1 liter ready-to-hang.
Osmolite HN	31.3 Cal/fl. oz.	sodium and calcium caseinates, soy protein isolate	hydrolyzed cornstarch	MCT, corn and soy oils	300	12.9	pro - 16.7% cho - 53.3% fat - 30.0%	rtf.: 32, 8 fl. oz., 1 liter ready-to-hang.

1/ At normal dilution.

Appendix C-2: Medical Foods: Complete Special Diets (Contd.)

Product	Caloric Density a Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/Qt	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
1/								
** Ross Laboratories								
Pediasure	30.0 Cal/fl. oz.	whey protein, sodium caseinate	corn syrup solids, sucrose	high oleic safflower oil, MCT	325	13.2	pro - 12% cho - 44% fat - 44%	rtf.: 8 fl. oz.
Pulmocare	44.4 Cal/fl. oz.	sodium and calcium caseinates	sucrose, hydrolyzed cornstarch	corn oil	490	18	pro - 16.7% cho - 28.1% Fat - 55.2%	rtf.: 8 fl. oz.
Two Cal HN	59.1 Cal/fl. oz.	sodium and calcium caseinates	hydrolyzed cornstarch, sucrose	corn oil, MCT	690	18	pro - 16.7% cho - 43.2% fat - 40.1%	rtf.: 8 fl. oz.
Vital High Nitrogen	29.6 Cal/fl. oz.	partially hydrolyzed whey, meat and soy amino acids	hydrolyzed cornstarch, sucrose	safflower oil, MCT	500	11.3	pro - 16.7% cho - 73.9% fat - 9.4%	pwd.: carton of 24 packets, 2.79 oz. each.
** Sandoz Nutrition								
Fiber Source	35.5 Cal/fl. oz.	sodium and calcium caseinates	hydrolyzed cornstarch	MCT, canola oil	390	11.35	pro - 14% cho - 56% fat - 30%	rtf.: 8.45 fl. oz.
Fiber Source HN	35.5 Cal/fl. oz.	sodium and calcium caseinates	hydrolyzed cornstarch,	MCT, canola oil	390	11.35	pro - 18% cho - 52% fat - 30%	rtf.: 8.45 fl. oz.

1/ At normal dilution.

Appendix C-2: Medical Foods: Complete Special Diets (Contd.)

Product	Caloric Density at Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H ₂ O	Iron Mg/Qt	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
1/								
** Sandoz Nutrition								
Isosource	35.5 Cal/fl. oz.	sodium and calcium caseinates, soy protein isolate	hydrolyzed cornstarch	MCT, canola oil	360	11.35	pro - 14% cho - 56% fat - 30%	rtf.: 8.45 fl. oz.
Isosource HN	35.5 Cal/fl. oz.	sodium and calcium caseinates, soy protein isolate	hydrolyzed cornstarch	MCT, canola oil	330	11.35	pro - 18% cho - 52% fat - 30%	rtf.: 8.45 fl. oz.
Isotein HN	35.5 Cal/fl. oz.	delactosed lactalbumin, sodium caseinate	hydrolyzed cornstarch, fructose	soybean oil, MCT	300	12	pro - 22.8% cho - 52.6% fat - 25.7%	pwd.: case of 6 packets, 2.9 oz. each.
Meritene Liquid	28.4 Cal/ fl. oz.	sweet skim milk, sodium caseinate	lactose, hydrolyzed cornstarch, sucrose	corn oil	505 - 570	13.6	pro - 24% cho - 46% fat - 30%	rtf.: 8 fl. oz.
Precision Isotonic Diet	31.25 Cal/fl. oz.	egg white solids, sodium caseinate	maltodextrin, sucrose	partially hydrogenated soybean oil	300	12	pro - 12% cho - 60% fat - 28%	pwd.: carton of 6 packets, 2.06 oz. each.
Resource Instant Crystals	31.25 Cal/fl. oz.	sodium and calcium caseinates, soy protein isolate	maltodextrin, sucrose	hydrogenated soy oil	450	9	pro - 14.0% cho - 54.5% fat - 31.5%	pwd.: case of 24 packets, 1.5 to 2.1 oz. each, depending on flavor.

1/ At normal dilution.

Appendix C-2: Medical Foods: Complete Special Diets (Contd.)

Product	Caloric Density a Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/Qt	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
1/								
** Sandoz Nutrition								
Resource Liquid	31.25 Cal/fl. oz.	sodium and calcium caseinates, soy protein isolate	maltodextrin, sucrose	corn oil	430	9	pro - 14.0% cho - 54.5% fat - 31.5%	rtf.: 8 fl. oz.
Resource Plus	44.38 Cal/fl. oz.	sodium and calcium caseinates, soy protein isolate	maltodextrin, sucrose	corn oil	600	13.6	pro - 14.7% cho - 53.3% fat - 32.0%	rtf.: 8 fl. oz.
** Sherwood Medical								
Comply	44.6 Cal/fl. oz.	sodium and calcium caseinates	hydrolyzed cornstarch	corn oil	410	17	pro - 16% cho - 48% fat - 36%	rtf.: 8.4, 33.5 fl. oz.
Magnacal	59.5 Cal/fl. oz.	sodium and calcium caseinates	maltodextrin, sucrose	partially hydrogenated soy oil	590	17	pro - 14% cho - 50% fat - 36%	rtf.: 4, 8.4 fl. oz.
1/ At normal dilution.								

Appendix C-3: Medical Foods: Complete Elemental Diets

Product	Caloric Density @ Normal Dilution	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg/Qt	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
1/								
** Kendall McGaw Laboratories								
Traum-Aid	29.56 Cal/fl. oz.	essential and nonessential amino acids	maltodextrin	MCT, partially hydrogenated soybean oil	760	5.68	pro - 22.4% cho - 66.4% fat - 11.2%	pwd.: case of 24 packets, 126 grams each.
** Mead Johnson Nutritionals								
Criticare HN	31.3 Cal/fl. oz.	hydrolyzed casein, amino acids	maltodextrin, modified cornstarch	safflower oil	650	8.8	pro - 14.0% cho - 81.5% fat - 4.5%	rtf.: 8 fl. oz.
** Norwich Eaton Pharmaceuticals, Inc.								
Tolerex	29.6 Cal/fl. oz.	free amino acids	predigested carbohydrates	safflower oil	550	9.5	pro - 8.2% cho - 90.5% fat - 1.3%	pwd.: carton of 6 packets, 80 grams each.
Vivonex T.E.N.	29.6 Cal/fl. oz.	free amino acids	predigested carbohydrates	safflower oil	630	8.5	pro - 15.3% cho - 82.2% fat - 2.5%	pwd.: carton of 10 packets, 80.4 grams each.
** Sherwood Medical								
Accu-pep HPF	29.85 Cal/fl. oz.	hydrolyzed lactalbumin	maltodextrin	MCT, corn oils	490	10.7	pro - 16.0% cho - 75.5% fat - 8.5%	pwd.: 128 gram pouches

1/ At normal dilution

Appendix C-4: Medical Foods: Incomplete Modular Diets

Product	Caloric Density Per 100 Grams	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg	Caloric Distribution	Packaging
=====								
** Mead Johnson Nutritional								
Casec	370	soluble calcium caseinate	0	negligible	N/A	0	pro - 95% fat - 5%	pwd.: 2.5 oz., yields 15 packed, leveled tablespoons.
MCT Oil	830	0	0	medium chain triglycerides	N/A	0	fat - 100%	liq.: 1 qt. (bottle).
Moducal	380	0	maltodextrin	0	N/A	0	cho - 100%	pwd.: 13 oz., yields 46 leveled tablespoons
** Ross Laboratories								
Polydose	380	0	glucose polymers	0	N/A	0	cho - 100%	liq.: 4.2 fl. oz. (43% solution) pwd.: 12.3 oz., yields 58 leveled tablespoons.
ProMod	560	whey protein concentrate	lactose	soy lecithin	N/A	0	pro - 71% cho - 10% fat - 19%	pwd.: 9.7 oz., yields 68 leveled tablespoons.
** Sherwood Medical								
Propac	0	whey protein concentrate	lactose	milk fat	N/A	0	pro - 76% cho - 6% fat - 18%	pwd.: 20 gram packets, 350 grams, yields 87.5 leveled tablespoons per can.
Sumacal	0	0	maltodextrin	0	N/A	0	cho - 100%	pwd.: 400 grams, yields 80 leveled tablespoons.

Appendix C-4: Medical Foods: Incomplete Modular Diets (Contd.)

Product	Caloric Density Per 100 Grams	Protein Source	Carbohydrate Source	Fat Source	Osmolality mOsm/Kg H2O	Iron Mg	Caloric Distribution	Packaging
=====	=====	=====	=====	=====	=====	=====	=====	=====
** Sherwood Medical								
Microlipid	0	0	0	safflower oil	N/A	0	fat - 100 %	liq.: 120 milliliter bottle
** Wyeth-Ayerst Laboratories								
"EDW" (Electrodialyzed Whey)	390	electro- dialyzed whey	lactose	negligible	N/A	0	pro - 35.7% cho - 57.4% fat - 6.9%	pwd.: 350 grams, yields 70 leveled tablespoons.

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Explanation of Initials

Carnation Company (CC)
Gerber Products Company (GPC)
Kendall McGaw Laboratories (KML)
Loma Linda Foods (LLF)
Mead Johnson Nutritionals (MJN)
Norwich Eaton Pharmaceutical (NEP)
Ross Laboratories (RL)
Sandoz Nutrition (SN)
Sherwood Medical (SM)
Wyeth-Ayerst Laboratories (WAL)

-A, B-

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